92-453

Supreme Court, U.S.
FILED
SEP 15 1992
OFFICE OF THE CLERK

NO. 92-

IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1992

ANTHONY MAZUR AND EDNA MAZUR AS PARENTS AND GUARDIANS OF LISA MARIE MAZUR, A MINOR, AND ANTHONY MAZUR AND EDNA MAZUR, IN THEIR OWN RIGHT,

Petitioners,

v.

MERCK & CO., INC.,

Respondent.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

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QUESTIONS PRESENTED

Whether the court of appeals improperly encroached upon the province of the Pennsylvania state appellate courts by deciding for itself an important and novel aspect of Pennsylvania's law of products liability when a Pennsylvania appellate court, sitting *en banc*, is -- even as this Court considers the instant petition -- deciding that same issue of state law?

Whether the court of appeals clearly misinterpreted Pennsylvania's law of products liability by merging negligence concepts with strict liability principles and by permitting a pharmaceutical manufacturer to delegate its duty to warn the parents of school children of the risks of an unavoidably unsafe vaccine?

Whether a misinterpretation of Pennsylvania's products liability law by the court of appeals, functionally precluding school children and their parents from obtaining effective redress for catastrophic injuries suffered as a result of participating in a mass immunization program involving an unavoidably unsafe vaccine, warrants the exercise of this Court's certiorari jurisdiction?

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ANTHONY MAZUR AND EDNA MAZUR
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PETITION FOR A WRIT OF CERTIORARI TO
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The petitioners, Anthony Mazur and Edna Mazur as parents and guardians of Lisa Marie Mazur, a minor, and Anthony Mazur and Edna Mazur, in their own right, respectfully pray that a Writ of Certiorari issue to review the Judgment and Opinion of the United States Court of Appeals for the Third Circuit entered on May 20, 1992.

OPINIONS BELOW

The opinion of the Court of Appeals for the Third Circuit is reported at 964 F.2d 1348 (3d Cir. 1992), and is reprinted in the appendix hereto at A1–82.[1]

The opinion of the United States District Court for the Eastern District of Pennsylvania granting summary judgment on June 27, 1991 is reported at 767 F. Supp. 697 (E.D. Pa. 1991) and is reprinted in the appendix hereto at A83–153. The opinion of the United States District Court for the Eastern District of Pennsylvania denying summary judgment on June 29, 1990 is reported at 742 F. Supp. 239 (E.D. Pa. 1990), and is reprinted in the appendix hereto at A154–254.

STATEMENT OF JURISDICTION

The jurisdiction of this Court to review the judgment of the Court of Appeals for the Third Circuit entered on May 20, 1992 is invoked pursuant to 28 U.S.C. § 1254(1) (1988). A Petition For Rehearing was denied by the court of appeals on June 18, 1992.

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[1]Citations to the Appendix, filed in conformity with Supreme Court Rule 14.1(k), shall be designated herein as ("A__").

STATEMENT OF THE CASE

Procedural History

Petitioners (hereinafter "the Mazurs") filed a civil action in the Court of Common Pleas of Philadelphia County, Philadelphia, Pennsylvania on October 18, 1985 (October Term, 1985, No. 2515). Based on the parties' diversity of citizenship, Respondent (hereinafter "Merck") removed the claim upon petition to the United States District Court for the Eastern District of Pennsylvania on November 1, 1985. On May 8, 1989, Merck filed a motion for summary judgment and to exclude expert testimony.

On June 29, 1990, the district court issued an order and opinion denying the motion for summary judgment as to the federal preemption and statute of limitations issues, and reserving judgment on the motion to exclude expert testimony and the motion for partial summary judgment on the Mazurs' failure to warn claims. *Mazur v. Merck & Co.*, 742 F. Supp. 239, 266 (E.D. Pa. 1990) (A253-54). The order also extended to the parties sixty (60) additional days to engage in further limited discovery and the right to supplement their respective filings. *Id.* Merck filed a supplemental motion for summary judgment and to exclude expert testimony on September 17, 1990.

On June 27, 1991, the district court issued an order and opinion granting Merck's motion for summary judgment limited to the issue of whether Merck breached its duty to warn the Mazurs of the risks and benefits of Merck's measles-mumps-rubella vaccine (hereinafter "M-M-R II"). *Mazur v. Merck & Co.*, 767 F. Supp. 697, 715 (E.D.Pa. 1991) (A153). The district court held that under Pennsylvania law a school nurse can be and

in this case was a "learned-intermediary" and that Merck made an adequate warning available to the school nurse, thereby discharging Merck's duty to warn the Mazurs of the possible adverse reactions to M-M-R II. *Id.* at 715 (A153). The Mazurs timely filed an appeal to the United States Court of Appeals for the Third Circuit.

On May 20, 1992, the court of appeals, in an opinion authored by the Honorable Anthony J. Scirica, held that under Pennsylvania law the school nurse present at the immunization site was not a learned intermediary in law or in fact and, therefore, warnings regarding M-M-R II were required to be given directly to the Mazurs. *Mazur v. Merck & Co.*, 964 F.2d 1348, 1355-61 (3d Cir. 1992) (A35-47). It was further held, however, that because M-M-R II was an unavoidably unsafe pharmaceutical product, Merck's duty to warn of the vaccine's inherent dangers could be delegated to a third party and Merck's responsibility for the failure of the third party to warn the Mazurs of M-M-R II's risks would be analyzed pursuant to the negligence standard set forth in section 388 of the RESTATEMENT (SECOND) OF TORTS, rather than pursuant to the strict liability standard of section 402A of the RESTATEMENT (SECOND) OF TORTS. 964 F.2d at 1364-69 (A69-82).

Applying section 388's negligence standard of reasonable care to the facts of the instant case, the court of appeals held that Merck acted reasonably and satisfied its duty to warn in the mass immunization context as a matter of law by contracting with the Centers for Disease Control (hereinafter "CDC") to provide proper warnings to the ultimate recipients (or their parents) of the risks of M-M-R II. Accordingly, the court of appeals dismissed the Mazurs' claims and affirmed the district court's order granting

summary judgment for Merck. Based on the belief that the Court of Appeals for the Third Circuit has misconstrued Pennsylvania's strict liability law and the fact that one of the cases upon which the panel relied was scheduled for reargument before the Superior Court of Pennsylvania *en banc*, the Mazurs requested reargument before the court of appeals *en banc*. On June 18, 1992, the Third Circuit denied the Mazurs' petition for reargument.

Facts Relevant To The Issues Presented

On February 26, 1982, Plaintiff Lisa Mazur (hereinafter "Lisa"), a twelve year old sixth grader in the Philadelphia public school system, was inoculated with M-M-R II (a vaccine to prevent measles, mumps and rubella) in a mass immunization program conducted by the Philadelphia School District and the Philadelphia Health Department. The M-M-R II vaccine used in the immunization program was manufactured by Merck and was purchased by the Philadelphia Health Department from the CDC.

Although a school nurse was present at the time that the M-M-R II vaccine was administered by a member of the Philadelphia Health Department, there was no physician in attendance to act as a "learned intermediary" to assess Lisa medically, to balance the risks and benefits of the vaccine in light of her medical condition and needs, and to obtain her "informed consent" to receive the vaccine. Importantly, at the time of Lisa's inoculation, her immunological condition was compromised due to a lengthy illness for which she was treated with a corticosteroid, a known contra-indicator for administration of the M-M-R II vaccine.

Although Merck obligated the CDC by contract to provide proper warnings to the ultimate vaccine recipients (or to the parents thereof), Lisa and her parents did not receive any information regarding the health risks and benefits associated with M-M-R II. Seventeen months after receiving the inoculation, Lisa was diagnosed as suffering from subacute sclerosing panencephalitis (hereinafter SSPE), a slowly progressing, ultimately fatal, neurological illness whose only scientifically recognized causes are natural measles virus and measles vaccine. Today, Lisa requires round-the-clock custodial care. The severe and irreversible nature of Lisa's illness has emotionally and financially devastated the Mazur family.

REASONS FOR GRANTING OF THE WRIT OF CERTIORARI

I.

THE COURT OF APPEALS IMPROPERLY ENCROACHED UPON THE PROVINCE OF THE PENNSYLVANIA STATE APPELLATE COURTS BY DECIDING FOR ITSELF AN IMPORTANT AND NOVEL ASPECT OF PENNSYLVANIA'S LAW OF PRODUCTS LIABILITY WHEN A PENNSYLVANIA APPELLATE COURT, SITTING *EN BANC*, IS -- EVEN AS THIS COURT CONSIDERS THE INSTANT PETITION -- DECIDING THAT SAME ISSUE OF STATE LAW

Federal courts in diversity cases must forecast and apply state law in all cases within their jurisdiction in which federal law does not govern. *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938). *See also* Rules of Decision Act, 28 U.S.C. § 1651 (1949). The

federal courts must not substitute their judgment for the law of the state, to the extent that the law of the state can be determined. *Fidelity Union Trust Co. v. Field*, 311 U.S. 169, 178 (1940). Moreover, the federal courts must exercise care to ensure that they do not encourage or allow for the development of a "double system of conflicting laws" in the same state that might deprive a litigant of the law as established by the forum state simply because the matter was removed to the federal court system by an opponent. *Guaranty Trust Co. of N.Y. v. New York*, 326 U.S. 99, 112 (1945).

As a corollary to the *Erie* doctrine, federal jurisprudence also recognizes "a doctrine of abstention... whereby the federal courts... restrain their authority because of a 'scrupulous regard for the rightful independence of the state governments....'" *Railroad Comm'n of Texas v. Pullman Co.*, 312 U.S. 496, 501 (1941) (emphasis added). Thus, in *Pullman* this Court abstained from deciding a question of federal constitutional law and remanded the case to the district court with instructions to the parties to litigate certain state law questions in state court. *Id.* at 501–02. In a similar vein, this Court has stayed federal proceedings in diversity cases in order to minimize federal intrusion in the development of state law. *Louisiana Power & Light Co. v. City of Thibodaux*, 360 U.S. 25, 31 (1959) (proceedings stayed pending prompt steps to secure declaratory judgment), *Clay v. Sun Ins. Office Ltd.*, 363 U.S. 207, 212 (1960) (unresolved state law question was appropriately certified by federal court to state court for determi-

nation).[2] Thus, federal courts have a long standing obligation, based upon the *Erie* doctrine and principles of abstention, to use restraint when attempting to forecast state law.

In the instant case, the Court of Appeals for the Third Circuit had no clear precedent to base its decision that Pennsylvania does not recognize a distinction between defective products and negligent conduct in strict liability failure to warn cases. The only case in Pennsylvania that has squarely addressed the strict liability of a pharmaceutical manufacturer in a failure to warn case involving an unavoidably unsafe product is *Hahn v. Richter*, No. 00019 PHL 1991, 1992 Pa. Super. LEXIS 275 (Pa. Super. Ct., Feb. 13, 1992). In a two–to–one decision, the Superior Court panel in *Hahn* found that in a failure to warn prescription drug case, the jury instructions under strict liability and negligence concepts were not different because "[t]he standard to be applied in determining whether an adequate and proper warning was provided is the negligence standard of reasonable care." *Id.* at 4–5. However, in a strong and persuasive dissenting opinion, Judge Del Sole exhaustively reviewed the Pennsylvania cases relating to

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[2]Notably, Pennsylvania has not adopted a certification statute. Although twenty–six states, through state constitutional provisions or by statute, permit federal courts to certify questions concerning state law to state courts, none of the states constituting the Third Circuit permits certification of state law questions by the court of appeals. (The Delaware State Constitution does permit the United States District Court for the District of Delaware to certify state law questions. Del. Const. art. IV, § 11 (9)). Because there is no procedure for certifying state law questions in Pennsylvania, the Third Circuit must be particularly mindful of the need to exercise restraint when exploring unsettled waters of Pennsylvania state law.

duty to warn in section 402A cases and concluded that there is a total lack of support in case law "for merging all failure to warn claims under one negligence standard...." *Id.* at 12. (Del Sole, J., dissenting).

On April 23, 1992, the Pennsylvania Superior Court granted reargument *en banc* in *Hahn* thereby signaling that the Court has a material question affecting the validity of the Superior Court panel's holding. *Cf.* Pa.R.App.P. 2543 (Considerations Governing Allowance of Reargument). The Court of Appeals for the Third Circuit abused its discretion in failing to exercise due and proper restraint in light of the *en banc* reargument granted in *Hahn*. Under this circumstance, the court of appeals should have awaited the ruling by the Pennsylvania appellate court which will determine how Pennsylvania law should be applied to the facts in this case.[3]

The instant matter merits review by this Court not only because it is clear that the Third Circuit court incorrectly determined the law of Pennsylvania, *see, infra*, pp. 10–17, but because there is a great likelihood that the Superior Court of Pennsylvania, *en banc*, will hold that negligence principles are inapplicable to a strict liability failure to warn claim involving prescription drugs. In the event of such a ruling while the instant petition is pending,

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[3]If the court of appeals was unaware that the Superior Court of Pennsylvania granted reargument *en banc* in *Hahn* on April 23, 1992 when it issued its opinion on May 20, 1992, it was certainly made aware of *Hahn's* procedural history by the Mazurs' application for reargument. Reargument in *Hahn* was held before the Superior Court of Pennsylvania on September 9, 1992.

this Court should reverse the decision of the Third Circuit court. *Vandenbark v. Owens Illinois Glass Co.*, 311 U.S. 358, 543 (1941) ("Intervening and conflicting decisions will... cause the reversal of judgments which were correct when entered."). Alternatively, this Court may decide to vacate the judgment below and remand the case to the Third Circuit to reconsider its ruling in light of the decision in *Hahn*. *See Huddleston v. Dwyer*, 322 U.S. 232, 238 (1944) (Doubts about the correctness of a federal court interpretation of a state law raised by an intervening state court decision will allow the Supreme Court to vacate the judgment below and remand the case to the court of appeals for reconsideration).

II.

THE COURT OF APPEALS CLEARLY MISINTERPRETED PENNSYLVANIA'S LAW OF PRODUCTS LIABILITY BY MERGING NEGLIGENCE CONCEPTS WITH STRICT LIABILITY PRINCIPLES AND BY PERMITTING A PHARMACEUTICAL MANUFACTURER TO DELEGATE ITS DUTY TO WARN THE PARENTS OF SCHOOL CHILDREN OF THE RISKS OF AN UNAVOIDABLY UNSAFE VACCINE

The strict liability standard for vendors began at common law with the imposition of a high degree of responsibility upon the victualers, vintners, brewers, butchers, cooks, and other persons who supplied food and drink to the public. Today, that high degree of responsibility has evolved to cover all products which, if defective, may be expected to cause physical harm to the consumer. *See* RESTATEMENT (SECOND) OF TORTS § 402A comment b (1985). However, because of the complexities of the

human body and limitations of medical science, certain medical products cannot be made safe for all consumers regardless of the care exercised in their design and manufacture. The archetypical product that is incapable of being made safe is the vaccine. In effect, vaccines are unsafe products whose production is justified because of the great overall public health benefit resulting from their use. Comment k to the RESTATEMENT (SECOND) OF TORTS § 402A thus instructs:

> The seller of such [vaccine] products, again *with the qualification that* they are properly prepared and marketed, and *proper warning is given*, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

(Emphasis added).

This case, for which review by this Court is sought, involves a young girl's severe and permanent brain injury which was caused by inoculation with the measles component of a vaccine manufactured by Merck. In reversing the district court, the court of appeals ruled that the mass immunization exception to the learned intermediary doctrine applied, requiring Merck to warn Lisa Mazur's parents directly of the risks and benefits of

inoculation with M-M-R II in order to escape liability for the tragic consequences of an adverse drug reaction. *Mazur v. Merck & Co.*, 964 F.2d 1348, 1364 (3d Cir. 1992) (A61). However, the court of appeals further determined that under Pennsylvania law, the court should treat all section 402A strict liability failure to warn claims, where vaccines or prescription drugs cause injury or death, as negligence claims. *Id.* at 1355, (A23-25). In other words, the court of appeals decided that as a matter of Pennsylvania state law, the discharge of a pharmaceutical manufacturer's duty to warn the parents of school children of the serious health risks posed by a vaccine is to be judged by negligence -- and not strict liability -- standards.

In support of its prediction of how the Pennsylvania courts would interpret Pennsylvania law concerning the elements of a strict liability failure to warn claim, the court of appeals cited two negligence cases wherein strict liability was not in issue. *Id.* at 1354 (A20-23) (citing *Incollingo v. Ewing*, 282 A.2d 206 (Pa. 1971) and *Baldino v. Castagna*, 478 A.2d 807 (Pa. 1984)). In so doing, the court of appeals ignored the clear weight of authority demonstrating that Pennsylvania adheres to a formal product/conduct distinction in evaluating failure to warn claims founded upon strict liability.

Courts in Pennsylvania have long recognized the theoretical dam between notions of negligence and strict "no fault" liability. *Walton v. Avco Corp.*, 1992 WL 2795, 8 (Pa. May 22, 1992). ("This Court has continually fortified the theoretical dam between the notions of negligence and strict 'no fault' liability."); *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 899 (Pa. 1975) ("The crucial difference between strict liability and negligence is that the existence of due care...is irrelevant.");

Kuisis v. Baldwin-Lima-Hamilton Corp., 319 A.2d 914, 918 (Pa. 1974) ("The principle of strict liability...eliminate[s] the issue of negligence from the case."); *Salvador v. Atlantic Steel Boiler Co.*, 319 A.2d 903, 906–907 (Pa. 1974) ("[402A] imposes liability on the seller or manufacturer of a defective product regardless of the lack of proven negligence."); *Harford Mut. Ins. Co. v. Moorhead*, 578 A.2d 492, 501 (Pa. Super. Ct. 1990) ("Pennsylvania courts consistently analyze the negligence/failure to warn and strict liability/failure to warn causes of action separately, treating conduct-related counts apart from product-related counts.") (citations omitted); *Carrecter v. Colson Equip. Co.*, 499 A.2d 326, 330 n.8 (Pa. Super. Ct. 1985) ("[W]e prefer the terminology 'inadequate warnings' to 'failure to warn' [in a strict liability case] because the latter language suggests a breach of duty in a way which tends to connote negligence."); *Dambacher by Dambacher v. Mallis*, 485 A.2d 408, 428 (Pa. Super. Ct. 1984). ("[W]e hold...that in a strict liability case, principles of negligence have no place."). In fact, it has been observed that the "Pennsylvania Supreme Court, perhaps more than any other state appellate court in the nation, has been emphatic in divorcing negligence concepts from products liability doctrine." *Harford Mut.*, 578 A.2d at 500 (quoting *Staymates v. ITT Holub Indus.*, 527 A.2d 140, 144 (Pa. Super. Ct. 1987)).

The Third Circuit itself has previously recognized Pennsylvania's distinction between negligence and strict liability concepts. *See, e.g., Holloway v. J.B. Sys., Ltd.*, 609 F.2d 1069, 1073 (3d Cir. 1979) ("[W]e emphasize that negligence concepts such as... 'reasonable care' have no place in suits brought under § 402A.... We read *Azzarello [v. Black Bros. Co.*, 391 A.2d 1020 (1978)] as a signal that evidence and jury instructions regarding

negligence concepts should be kept out of cases brought under § 402A.") (footnote omitted).

By holding that the negligence standard of section 388 of the RESTATEMENT (SECOND) OF TORTS[4] is applicable to a pharmaceutical manufacturer's duty to warn concerning unavoidably unsafe products -- regardless of whether a lawsuit is premised upon a theory of negligence or upon a theory of strict

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[4]Section 388 of the RESTATEMENT (SECOND) OF TORTS states:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
>
> (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
>
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
>
> *(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.*

(Emphasis added).

liability under § 402A[5] -- the Third Circuit badly misinterpreted and misapplied the decisions of the Supreme Court of Pennsylvania in *Incollingo v. Ewing* and *Baldino v. Castagna* (both of which involved negligence claims only),[6] and departed from the

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[5]Section 402A of the RESTATEMENT (SECOND) OF TORTS provides:

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> (a) the seller is engaged in the business of selling such a product, and
>
> (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
>
> (2) The rule stated in Subsection (1) applies although
>
> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

[6]Neither *Incollingo* nor *Baldino* are apposite to this case. Both of those cases involved claims where adequate warnings reached a learned intermediary, but the warnings were counteracted by the conduct of the pharmaceutical company in minimizing the risks of the product in subsequent sales and promotion campaigns. Thus, 402A strict liability for failure to warn was not in issue in either case; the sole question was whether the conduct of the pharmaceutical companies' agents in minimizing the risks of the product was negligent. Accordingly, neither

(continued...)

long-standing principle of Pennsylvania state products liability law that negligence has no place in strict liability cases.

No Pennsylvania court has ever found that a manufacturer's duty to warn of a product's risks and benefits is delegable to a third party under a strict liability analysis, regardless of how reliable that third party appears to be. On the contrary, a plurality of the Supreme Court of Pennsylvania has expressly determined that "[t]he duty to provide a non-defective product is non-delegable." *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 903 (Pa. 1975). *Accord Petty v. United States*, 740 F.2d 1428 (8th Cir. 1984) (in mass-immunization context duty to warn ultimate recipient of risks and benefits of vaccine is absolute and non-delegable.) The Third Circuit summarily dismissed the holding in *Berkebile* by finding it inapplicable in prescription drug cases. *Mazur*, 964 F.2d at 1365, A63-64. In other words, the Third Circuit interpreted Pennsylvania law as foreclosing action for strict liability when prescription drugs are the product at issue. However, no Pennsylvania court has ever immunized prescription drug products from the application of 402A strict liability principles.

For all of the foregoing reasons, the Third Circuit's decision to legislate its own exception to Pennsylvania's state law

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[6](...continued)
case abrogated the fundamental requirement of a drug manufacturer to distribute its product properly prepared and accompanied by adequate warnings to the product user, nor did they abrogate the premise of strict liability pursuant to 402A, Comment k of the RESTATEMENT (SECOND) OF TORTS.

governing products liability should be promptly corrected. Insofar as the decision is grossly at odds with Pennsylvania's state law, it should be reversed.

III.

THE MISINTERPRETATION OF PENNSYLVANIA'S PRODUCTS LIABILITY LAW BY THE COURT OF APPEALS, FUNCTIONALLY PRECLUDING SCHOOL CHILDREN AND THEIR PARENTS FROM OBTAINING EFFECTIVE REDRESS FOR CATASTROPHIC INJURIES SUFFERED AS A RESULT OF PARTICIPATING IN A MASS IMMUNIZATION PROGRAM INVOLVING AN UNAVOIDABLY UNSAFE VACCINE, WARRANTS THE EXERCISE OF THIS COURT'S CERTIORARI JURISDICTION

The practical effect of the decision of the court of appeals is to carve out an unprecedented exception to the fundamental duty of a manufacturer to warn a consumer of the risks and benefits of a prescription drug when the drug is administered in a mass immunization setting to school children under the auspices of a federal agency. In effect, it leaves the innocent but injured child without an adequate right of recovery when warnings do not reach the child or the child's parents. Such a holding is diametrically opposed to the broad policy considerations which underlie the imposition of strict liability.

The risk of loss between the completely innocent consumer and the manufacturer of an injury-causing product traditionally has been imposed on the manufacturer, who is best able to pay

for the damages caused. In this case, however, the Third Circuit has placed the risk of loss not on the manufacturer, but on the innocent child who is in the least likely position to pay for the harm suffered by the offending product.[7] By contracting with the CDC to distribute and administer the measles vaccine that it produces, Merck has effectively insulated itself from the imposition of strict liability for its distributor's failure to give adequate warnings to consumers.

This Court has considered the substantive law of products liability under section 402A only once. *East River S.S. Corp. v. Transamerica Delaval, Inc.*, 476 U.S. 858 (1986). While in that case certiorari was granted to resolve a conflict among the courts of appeals sitting in admiralty, *id.* at 2298, this Court did recognize that products liability law in general has long been a part of the common law of torts and "grew out of a public policy

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[7]Absent gross negligence, the innocent and injured consumer (here, a twelve year old girl) is precluded from seeking compensation from the doctors or nurses administering the vaccine. 42 Pa. C.S.A. § 8334 (1978). In addition, no compensation is available from federal agencies (such as the CDC) because the creation and method of distributing vaccine warnings is a discretionary function. 28 U.S.C. § 1346 (b) (1976). By summarily disposing of this case in favor of Merck, the Third Circuit foreclosed Lisa from receiving any compensation whatever for her injuries, and severely limited the means by which other innocent and injured children like Lisa may be compensated in the future. Indeed, recovery for claims presented under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300 aa, *et seq.* (1988), are extremely limited for children in Lisa's position. Thus, even assuming that Lisa may have been qualified to present a claim under that Act, any recovery she may have obtained would have been severely limited.

judgment that people need more protection from dangerous products than is afforded by the law of warranty." *Id.* at 2299. The *East River* case highlights the social importance of the substantive development of products liability and the worthiness of accepting certiorari to consider such state law issues.

CONCLUSION

For all of the foregoing reasons, Petitioners respectfully request that this Court exercise its jurisdiction and grant a writ of certiorari.

Respectfully submitted by,

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September 16, 1992

APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

NO. 91-1613

ANTHONY MAZUR and EDNA MAZUR
as Parents and Guardians of LISA MARIE MAZUR,
as Minor, and ANTHONY MAZUR and EDNA MAZUR,
in their own right,

Appellants

v.

MERCK & CO., INC.

Appellees

Argued January 23, 1992

Before: STAPLETON, SCIRICA and ALITO,
Circuit Judges

OPINION OF THE COURT

SCIRICA, Circuit Judge.

In this products liability action appellants Lisa Mazur and her parents seek compensatory and punitive damages from appellee Merck & Co., Inc. for failure to warn that the use of its vaccine could result in serious neurological illness. The District Court entered summary judgment for Merck on the ground that it provided an adequate warning to a learned intermediary, and, in the alternative, exercised reasonable care to inform users of the risks of its vaccine by contractually obligating the United States Centers for Disease Control (CDC)[1] to warn

[1] The CDC is an arm of the Public Health Service of the United States Department of Health and Human Services. It is charged with protecting the public health of the nation by providing leadership and direction in the prevention and control of diseases and responding to emergencies. The CDC also provides assistance to state and local health agencies in the form

vaccinees directly. *Mazur v. Merck & Co.*, Inc., 767 F. Supp. 697 (E.D. Pa. 1991). Because we conclude that Merck satisfied its duty to warn by contractually obligating the CDC the warn vaccinees directly, we will affirm.

I.

In response to a measles epidemic in the late 1970s, the Philadelphia Department of Public Health proposed a regulation, later adopted by the School Board of Health, requiring all school children to be vaccinated against a variety of pediatric diseases. Under the regulation, school nurses were instructed to review the health records of about 300,000 students city-wide to determine which vaccines, if any, they needed, and to obtain written permission from students' parents for vaccination in appropriate cases.

(footnote no.1 continued...)

of project grants to assist them in activities aimed at eliminating certain diseases, including measles. *See* 42 U.S.C. § 247 (1988).

Where adequate proof of prior vaccinations or diseases was not forthcoming, students were considered unimmunized.

Based on a recommendation and information from the CDC, Dr. Robert G. Sharrar, a director of the Philadelphia health department, selected M-M-R II (MMR II) as the measles vaccine for the city's immunization program. MMR II is a live-virus vaccine for simultaneous immunization against measles, mumps, and rubella. It is a prescription drug and has been manufactured by Merck since 1978 under a license from the United States Food and Drug Administration.

The MMR II vaccine is distributed in vials containing an FDA-approved "package circular," describing the risks attendant to the vaccine's use. In April 1981 the package circular contained the following statement about the risk of contracting subacute sclerosing panencephalitis (SSPE), a fatal, slowly progressing neurological disease, from inoculation with the MMR II vaccine:

> There have been reports of [SSPE] in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccine distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5–10 cases of SSPE per million cases of measles. The results of a retrospective case–controlled study concluded by the [CDC] suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent risk of SSPE.

The package circular also contained the following paragraph on revaccination:

> Based on available evidence, there is no reason to routinely revaccinate children originally vaccinated when 12 months of age or older; however; children vaccinated when younger than 12 months of age should be revaccinated. The decision to revaccinate should be based on evaluation of each individual case.

The Philadelphia Health Department purchased the MMR II vaccine for the city's immunization program from

the CDC, which had purchased it from Merck. Merck was at first reluctant to sell its MMR II vaccine to the CDC, but relented after the CDC agreed to the following contractual provision:

> The [CDC] represents and agrees that it will (1) take all appropriate steps to assure that all vaccine supplied to various locations within the 50 states,. . .pursuant to the terms of this contract, shall be administered to each patient on the basis of an individualized medical judgment by a physician, or (2) take all appropriate steps to provide to such a patient (or to the patient's parent or guardian) meaningful warnings relating to the risks and benefits of vaccination, in form and language understandable to such patient, parent or guardian.[2]

Opting to proceed under the latter clause, the CDC drafted an "Important Information Statement," designed to inform parents of the risks of inoculation with the MMR II vaccine in lay terms. It then obligated state and local

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[2] The identical provision was contained in all three purchase agreements entered into between Merck and the CDC for use of the MMR II vaccine in the public health sector.

health agencies who purchased MMR II vaccine from it, including the Philadelphia Health Department, to distribute the Important Information Statement to vaccinees, parents, or their guardians. The Important Information Statement was distributed to nurses at a district-wide informational meeting on the city's immunization program, and was forwarded to parents by way of their children.

Lisa Mazur's mother claims that she never received the Important Information Statement, or any other document pertaining to the risks associated with use of the MMR II vaccine. But she admits to having been notified of the immunization program, and, in particular, receiving a letter from the school district explaining the program with an attached immunization record and written permission form. Mrs. Mazur neither signed nor returned the permission form.

Instead, she called Lisa's school principal and an official at the Board of Education, and told them that Lisa

was immunized for measles in 1973 and that she would not consent to her revaccination. Then, to prevent Lisa from being revaccinated, Mrs. Mazur kept her out of school for a week. But she eventually relented under pressure from school officials, and sent Lisa back to school. Shortly thereafter, students were immunized at Lisa's school, the Andrew J. Morrison School.

The immunization program was administered at the Morrison School by Edith B. Frederick, a registered nurse. Nurse Frederick was responsible for personally reviewing student health records to determine which students had been previously vaccinated and to check for medical conditions that might heighten the risks of vaccination. She also arranged the immunization forms that were sent home with students, including the Important Information Statement, distributed them to students, and collected the permission forms that were returned.

Students were inoculated at the Morrison School on February 26, 1982. They were led into the school gymnasium single file, one classroom at a time. Nurse Frederick and a technician who administered the vaccination shots were situated at a table. As students approached them, Nurse Frederick took each student's permission form, checked it against her health records, and informed the technician which vaccine to administer. Nurse Frederick also examined the "overall appearance" of students as they passed by her, and, sometimes, asked them how they felt. On average it took students three to four minutes to pass through the line and be vaccinated. No physician was present during the inoculation, or was any representative from either Merck or the CDC.

Although Nurse Frederick's records do not include a signed permission form for Lisa Mazur, they indicate that she was inoculated with the MMR II vaccine that day. On September 7, 1983, shortly after her fourteenth birthday,

Lisa was admitted to St. Christopher's Hospital for Children in Philadelphia because of "personality changes" and "abnormal movements." On November 2, 1983, she was diagnosed with SSPE.

On October 18, 1985, the Mazurs filed this action in the Philadelphia Court of Common Pleas seeking compensatory and punitive damages. Their complaint alleges negligence and strict liability claims against Merck under Pennsylvania law for, among other things, failure to provide an adequate warning. Merck removed the action to federal District Court, and moved for summary judgment on the Mazurs' failure to warn claims.

Merck contended that (1) the Mazurs' state law claims were preempted by the pervasive scheme of federal regulations governing the production, labeling, and distribution of vaccines; (2) the Mazurs' action was barred by Pennsylvania's two-year statute of limitations for tort claims; and (3) Merck met its duty to warn by informing

Dr. Sharrar of the risks associated with the MMR II vaccine, and, alternatively, obligating the CDC to ensure that the vaccine was administered by a physician or to provide meaningful warnings to vaccinees.

The District Court issued an opinion and order denying Merck's motion for summary judgment on the federal preemption and statute of limitations issues. *Mazur v. Merck & Co. (Mazur I)*, 742 F. Supp. 239 (E.D. Pa. 1990). But it reserved judgment on the issue whether Merck met its duty to warn, and instead allowed further discovery and additional filings on this matter. Merck then filed a supplemental motion for summary judgment, which the District Court granted. *Mazur v. Merck & Co. (Mazur II)*, 767 F. Supp. 697.

Drawing on its earlier opinion, the District Court held that (1) Merck had a "duty to exercise reasonable care to inform those for whose use [its MMR II vaccine] was supplied of the facts which make it dangerous"; (2) Nurse

Frederick acted as a learned intermediary, because she "made a considered medical judgment" as to which students should be vaccinated on February 26, 1982; (3) the package circular constituted an adequate warning; and (4) Merck reasonably relied on the CDC to see that users were informed of the risks of its MMR II vaccine directly. *Id.* Accordingly, the district court granted summary judgment for Merck.[3] This appeal followed.

II.

We have jurisdiction under 28 U.S.C. §1291. We are required to address two novel issues of Pennsylvania

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[3] Because the district court granted Merck's supplemental motion for summary judgment, it did not address the issue of proximate causation. *Mazur II*, 767 F. Supp. at 698 n.1. At oral argument, Merck asserted that, even assuming Merck breached its duty to warn, the Mazurs have failed to establish that this breach was a proximate cause of Lisa Mazur's condition. Because we conclude that Merck satisfied its duty to warn as a matter of law, we do not reach the issue of proximate causation.

products liability law: first, whether the learned intermediary rule extends to a registered nurse who supervises the vaccination of students as part of a city-wide immunization program; and second; whether a vaccine manufacturer may satisfy its duty to warn in the mass immunization context by contractually obligating the CDC to inform users of the risks of its vaccine directly.

Our review of the district court's thorough and careful opinions and order granting summary judgment is plenary. *Erie Telecommunications, Inc. v. City of Erie*, 853 F.2d 1084, 1093 (3d Cir. 1988). We apply the same principles governing the district court's determination whether to grant summary judgment:

> [W]e must be convinced that the prevailing party has successfully demonstrated "that there is not genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Moreover, all inferences must be drawn against the movant ... and in favor of the nonmovant.

Id. (citations omitted). Merck bears the "ultimate burden of showing the absence of a genuine issue as to any material fact." *Gans v. Mundy*, 762 F.2d 338, 343 (3d Cir.), *cert. denied*, 474 U.S. 1010 (1985). But if this standard is met, the burden shifts to the Mazurs to establish a "genuine issue of material fact." *Id.*

We apply Pennsylvania law and must predict how the Pennsylvania Supreme Court would decide this case. "The decisions of the Pennsylvania Superior Court, while not controlling, are "indicia of how the [Pennsylvania Supreme Court] might decide" the issue." *Bohus v. Beloff*, 950 F.2d 919, 924 (3d Cir. 1991) (quoting *McNasby v. Crown Cork & Seal Co.*, 888 F.2d 270, 281 (3d Cir. 1989)).

A.

Our first task is to determine whether the district court properly formulated Merck's duty to warn. As the district court noted, "ordinarily" Pennsylvania courts impose strict liability on manufacturers of products sold "in a defective condition unreasonably dangerous to the user or consumer" under section 402A of the *Restatement (Second) of Torts*.[4] Mazur I, 742 F.Supp. at 251 (citing *Incollingo*

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[4] §402A. Special Liability of Seller of Product for Physical Harm to User or Consumer.

> (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if
>
> > (a) the seller is engaged in the business of selling such a product, and
> >
> > (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it sold.
>
> (2) The rule stated in Subsection (1) applies although

v. Ewing, 282 A.2d 206, 219 (PA. 1971)). Products sold without adequate warnings of the risks attendant to their use are considered defective. *Id.; see Restatement (Second) of Torts* §402A cmt. h.

However, as the district court observed, "the strict liability rules for prescription drugs, such as vaccines, are somewhat different under Pennsylvania law." *Id.* These products fall into the category of "unavoidably unsafe products" set forth in comment K to section 402A of the *Restatement*.[5] *Id.* (citing *Incollingo*, 282 A.2d at 219).

> (a) the seller has exercised all possible care in the preparation and sale of his product, and
>
> (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

Restatement (Second) of Torts §402A (1965). Section 402A was adopted as the law of Pennsylvania in *Webb v. Zern*, 220 A.2d 853 (Pa. 1966).

[5] k. *Unavoidably unsafe products*. There are some products which, in the present state of human knowledge,

"Such a product, properly prepared, and accompanied by directions and warning, is not defective, nor is it unreasonably dangerous." *Restatement (Second) of Torts* §402A cmt. k.

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are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot be legally sold except to physicians, or under the prescription of the physician. . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper

(footnote no. 5 continued...)

warning is given, where the situation calls for it, is not held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known and apparently reasonable risk.

Restatement (Second) of Torts §402A cmt. k.

With respect to "unavoidably unsafe products," the district court said, the "strict liability principles of section 402A do not apply." *Mazur I*, 742 F. Supp. at 252. Instead, the district court held that section 388 of the *Restatement (Second) of Torts*[6] applies, regardless whether

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[6] §388. Chattel Known to be Dangerous for Intended Use.

> One who supplies directly or through a third person a chattel for another to use is subject to liability to

(footnote no. 6 continued...)

> those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
>
> > (a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
> >
> > (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

the plaintiff's failure to warn claim is founded in negligence or strict liability. Under that section, "the supplier has a *duty to exercise reasonable care* to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Id.* at 252 (quoting *Incollingo*, 282 A.2d at 220 n.8) (emphasis in original).

Thus, the district court concluded:

> Since the Mazurs assert that Merck is both strictly liable and liable for negligence in failing to warn them of the dangers of the MMR II inoculation, a liability analysis under either theory will depend on whether Merck complied with the "duty to exercise reasonable care to inform" the Mazurs of health risks associated with MMR II use.

Id. We agree.

Although the Mazurs apparently do not dispute that the MMR II vaccine is an "unavoidably unsafe product,"

> (c) *fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.*

Restatement (Second) of Torts §388 (emphasis added).

they argue that the district court erred by failing to distinguish between a prescription drug manufacturer's duty to warn in strict liability as opposed to negligence. According to the Mazurs, "[w]hen a particular product is not accompanied by an adequate warning, the product is defective and the manufacturer is strictly liable under section 402A, regardless of the care which the manufacturer took to ensure that proper warnings would accompany that product."

Although adequacy of warning is relevant to the determination whether a prescription drug manufacturer has met its duty to warn, the Pennsylvania Supreme Court has consistently formulated the prescription drug manufacturer's duty to warn under the section 388 "reasonableness" standard. The seminal case is *Incollingo v. Ewing*. There are the parents of a child who died after being administered Chloromycetin, a broad spectrum antibiotic, brought a negligent failure to warn claim against the prescription drug

manufacturer. The Pennsylvania Supreme Court began its analysis of the plaintiffs' failure to warn claim by looking to section 402A of the *Restatement*. However, because it found Chloromycetin to be an "unavoidably unsafe product," the court held that section 388 of the *Restatement* supplied the defendant's duty to warn. 282 A.2d at 22 & n.8.[7]

The Mazurs contend that *Incollingo* is inapposite because the plaintiffs' failure to warn claim in that case was founded in negligence, and the supreme court's conclusion

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[7] The *Incollingo* court explained:

> Since the strict liability rule of §402A is not applicable, the standard of care required is that set forth in §388 of the Restatement dealing with the liability of a supplier of a chattel known to be dangerous for its intended use. Under this section, the supplier has a duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous.

282 A.2d at 220 n.8.

that section 388 governed was based on the absence of a strict liability claim. However, the *Incollingo* court's conclusion that section 402A of the *Restatement* did not apply was based on its determination that Chloromycetin is within the category of "unavoidably unsafe products," not the absence of a strict liability failure to warn claim. Therefore, because the MMR II vaccine is an "unavoidably unsafe product," we believe *Incollingo* is controlling here.

Baldino v. Castagna, 478 A.2d 807 (Pa. 1984), is instructive. Although the underlying action in that case was founded in negligence, the Pennsylvania Supreme Court made clear that section 388 governs failure to warn claims founded in strict liability:

> In *Incollingo* we held that, assuming proper preparation and warning, a manufacturer of drugs is *not strictly liable* for unfortunate consequences attending the use of otherwise useful and desirable products which are attended with a known but apparently reasonable risk. *Id.* at 221. Rather, *such a manufacturer is liable only if he fails to exercise reasonable care to inform those for*

> *whose use the article is supplied of the facts which make it likely to be dangerous. Id.* at 220 n.8 (citing section 388 of the *Restatement (Second) of Torts).*

Id. at 810 (emphasis added). *See also White v. Weiner*, 562 A.2d 378, 384 (Pa. Super.) (applying section 388 to strict liability failure to warn claim), *aff'd without op.*, 583 A.2d 789 (Pa. 1991); *McDaniel v. Merck, Sharp & Dohme,* 533 A.2d 436, 445–46 (Pa. Super. 1987) (same). *But cf. Hartford Mut. Ins. Co. v. Moorhead*, 578 A.2d 492 (Pa. Super 1990).[8] Accordingly, we agree with the district

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[8] In *Hartford Mutual Insurance Co.* the Pennsylvania Superior Court distinguished between failure to warn claims founded in negligence and strict liability on the ground that a negligent failure to warn claim charges improper *conduct* whereas a strict liability failure to warn claim charges a defective *product.* 578 A.2d at 501. Significantly, the product at issue in that case -- sulphur strips used for making wine – is not within the category of "unavoidably unsafe products" set forth by comment k to section 402A of the *Restatement (Second) of Torts.* Therefore, the court had no occasion to invoke the section 388 "reasonableness" standard applied in *Incollingo v. Ewing.*

The Pennsylvania Superior Court made this clear in *Hahn v. Richter*, No. 00019, 1992 Pa. Super. LEXIS 275 (Pa. Super. Feb. 13, 1992). In that case the plaintiff brought a failure to warn claim against the manufacturer of Depo-Medrol, a corticosteroid prescribed to the plaintiff by his physician. The jury returned a verdict for the

(footnote no. 8 continued...)

defendant, finding that it did not *negligently* fail to warn users of the risks of Depo-Medrol. The plaintiff appealed on the ground that the jury should have been instructed separately on failure to warn in strict liability, but the Pennsylvania Superior Court affirmed. Because Depo-Medrol is "unavoidably unsafe," the court said that "[t]he standard of care to be applied in determining whether an adequate and proper warning was provided in the negligence standard of reasonable care." *Id.* at *4-7. One judge dissented on the grounds that Hartford Mutual Insurance Co., carved out a distinction between negligent and strict liability failure to warn claims, and, in any event, Depo-Medrol is not "unavoidably unsafe." *Id.* at *7-15 (Del Sole, J., dissenting).

Courts in other jurisdictions have distinguished between negligent and strict liability failure to warn claims on a conduct/product basis, *see, e.g., Petty v. United States,* 740 F.2d 1428, 1440-41 (8th cir. 1984) (applying Iowa law), though commentators have criticized this distinction as being based more on semantics than sound policy, *see* Henderson & Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn,* 65 N.Y.U.L. Rev. 265, 275-278 (1990); Keeton, *The Meaning of Defect*

court that Merck's duty to warn users of the risks of its MMR II vaccine is governed by section 388 of the *Restatement.* The more difficult question is whether the district court properly determined that, as a matter of law, Merck met its duty to exercise reasonable care to inform vaccinees of the risks of its MMR II vaccine on the facts here.

As the district court noted, it is established under Pennsylvania law that a prescription drug manufacturer may meet its duty to warn by providing an adequate warning to a "learned intermediary," as opposed to the general public or individual users. *Mazur I,* 742 F. Supp. at 252 (citing *Incollingo,* 282 A.2d at 220). A learned intermediary is one who exercises "individual medical judgment bottomed on a

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in Products Liability Law – A Review of Basic Principles, 45 Mo. L. Rev. 579, 586–87 (1980). In any event, at least in cases involving "unavoidably unsafe products," the Pennsylvania Supreme Court has not distinguished between a prescription drug manufacturer's duty to warn in negligence versus strict liability.

knowledge of both patient and palliative," but, according to the district court, need not be a physician. *Id.* (quoting *Reyes v. Wyeth Lab.*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974)).

Where vaccine is not dispensed by a learned intermediary, but to "all comers at mass clinics," courts in other jurisdictions have said that "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself, or by obligating the purchaser to give warning." *Id.* at 253 (quoting *Davis v. Wyeth Lab., Inc.*, 399 F.2d 121, 131 (9th Cir. 1968)). This has become known as the "mass immunization exception" to the learned intermediary rule. But, as the district court observed, is better viewed as one context where the prescription drug manufacturer is obligated to warn users directly. *Mazur II*, 767 F. Supp. at 700.

The district court held that Merck met its section 388 duty to warn by providing an adequate warning (the

package circular) to a learned intermediary (Nurse Frederick), and, in the alternative, by contractually obligating the CDC to see that its MMR II vaccine was administered by a physician or to provide meaningful warnings to vaccinees. We must determine whether either or both of these rulings are correct as a matter of law.

B. – LEARNED INTERMEDIARY

In *Mazur I* the district court predicted that "the Pennsylvania courts . . . would hold that in appropriate circumstances a nurse can act as a learned intermediary," but left for trial the determination whether Nurse Frederick acted as a learned intermediary under the facts here. 742 F. Supp. at 255. In *Mazur II,* however, the district court found that "[l]ooking at the totality of her qualifications and what she did, it is clear that Nurse Frederick was acting as a learned intermediary at the time of Lisa's inoculation."

767 F. Supp. at 711. The Mazurs challenge this conclusion both as a matter of law and fact.

The learned intermediary rule was first adopted by the Pennsylvania Supreme Court in *Incollingo v. Ewing,* 282 A.2d at 206. Under this rule,

> It is the duty of the prescribing physician to be fully aware of (1) the characteristics of the drug he is prescribing, (2) the amount of the drug which can be safely administered, and (3) the different medications the patient is taking. It is also the duty of the prescribing physician to advise the patient of any dangers or side effects associated with the use of the drug as well as how and when to take the drug. The warnings which must accompany such drugs are directed to the physician rather than to the patient-consumer as "[i]t is for the prescribing physician to use his independent judgment, taking into account the data supplied to him from the manufacturer, other medical literature, and any other sources available to him, and weighing that knowledge against the personal medical history of his patient, whether to prescribe a given drug."

Cayle v. Richardson-Merrell, Inc., 584 A.2d 1383 (Pa. 1991) (quoting *Makripodis v. Merrell-Dow*

Pharmaceuticals, Inc., 523 A.2d 374, 378 (Pa. Super. 1987) (internal quotation omitted)). *See also White v. Weiner,* 562 A. 2d 378.[9]

As the district court observed, courts in other jurisdictions have held that nurses may act as learned intermediaries under certain circumstances. *See, e.g., Rohrbough v. Wyeth Lab., Inc.* 719 F. Supp. 470 (N.D.W. Va. 1989), *aff'd,* 916 F.2d 970 (4th Cir. 1990); *Walker v.*

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[9] In *White* the Pennsylvania Superior Court explained that

> the rationale for th[e learned intermediary] rule is obvious: It is the physician who has the superior knowledge in the circumstances because he or she is able to balance the risks associated with the prescription drug against its utility "in light of his [or her] personal knowledge of the patient's medical history."

562 A.2d at 386 (quoting *Leibowitz v. Ortho Pharmaceutical Corp.,* 307 A.2d 449, 457 (Pa. Super. 1973)). *See generally* Rheingold, *Products Liability – The Ethical Drug Manufacturer's Liability,* 18 Rutgers L. Rev. 947, 987 (1964) (discussing the policies underlying the learned intermediary rule).

Merck & Co., 648 F. Supp. 931 (M.D. Ga. 1986), *aff'd without op.*, 831 F.2d 1069 (11th Cir. 1987).[10] To date, however, no Pennsylvania court has recognized that anyone other than a physician may be a learned intermediary.

In two recent cases Pennsylvania courts have declined to extend the learned intermediary rule to pharmacists. In *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.* the parents of a deformed infant brought a products liability action against the manufacturer of Bendectin, a prescription drug taken during the early stages of pregnancy to prevent nausea, and the pharmacy from whom the plaintiffs purchased the drug. Among other things, the plaintiffs alleged that the pharmacy "was strictly liable in tort as Bendectin was a defective product, unreasonably dangerous due to the absence of proper warnings." 523 A.2d at 375. The trial court granted

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[10] *See infra* note 18.

summary judgment for the pharmacy, and the Pennsylvania Superior Court affirmed on the ground that retail pharmacists have no independent duty to warn patient-consumers of the risks of prescription drugs they dispense. *Id.* at 378.

The Superior Court reasoned that "the warnings which are required to be given by the manufacturer must be directed to the physician," because it is for the physician to exercise his "independent medical judgment" to determine which drugs should be prescribed given the patient's medical history and condition. *Id.* Imposing an "independent duty to warn" on pharmacists would ill serve the purposes behind the learned intermediary rule, because "the retail pharmacist is in most instances unfamiliar with the medical history and condition of the patient-consumer and, in any event, is not a physician, trained in the diagnosis and treatment of diseases." *Id.* Thus, warnings by pharmacists "would be inadequate to enable the average

consumer to evaluate the benefits and risks attendant to the use of such drugs." *Id.* at 379.

The Pennsylvania Supreme Court adopted the reasoning of *Makripodis* in *Coyle v. Richardson-Merrell, Inc.* The facts of that case are almost identical to *Makripodis*: the parents of a deformed infant brought a products liability action against the manufacturer of Bendectin and the pharmacy from whom the plaintiffs purchased the drug. In *Coyle*, however, the plaintiffs did not allege that the pharmacy was strictly liable for failure to warn, but rather that it was strictly liable as the supplier of a defective product.[11] The trial court granted summary judgment for the pharmacy, and the Pennsylvania Superior Court and Supreme Court affirmed. 584 A.2d at 1384.

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[11]. As the *Coyle* court noted, "[i]t is not entirely clear in what sense . . . the drug was defective beyond that it allegedly carried a risk, of which no warning was given, of causing the child of the pregnant woman for whom it was prescribed of developing with malformed limbs." 584 A.2d at 1386.

The Supreme Court refused to impose strict liability upon pharmacists for failure to warn. The plaintiffs' argument, the court said, "g[a]ve scant attention to the rule of *Incollingo* and its rationale." *Id.* at 1386. For, "[u]nder that rule, information about the risks of medicines is provided to the person who most needs and can best evaluate it–the physician–to be shared with and explained to the patient in the context of his or her individual medical circumstances." *Id.*

As the Court explained, under the distribution system for prescription drugs, "[p]hysicians exercising sound medical judgment act as intermediaries . . ., preempting, as it were, the exercise of discretion by the supplier–pharmacist, and, within limits, by the patient–consumer." *Id.* "[I]t is not the pharmacist on whom the public 'is forced to rely' to obtain the products they need," but rather the physician. *Id.* at 1387. "Physicians act as exclusive intermediaries." *Id.*

We find the Pennsylvania courts' reasoning in *Makripodis* and *Coyle* instructive on whether the learned intermediary rule extends to nurses[12] under Pennsylvania law. Like pharmacists, nurses generally are not capable of providing the degree of individualized medical judgment rendered by physicians, and are not authorized independently to prescribe drugs.[13] This is because nurses

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[12] Pennsylvania law recognizes several types of health care professionals, many of which might generically be referred to as nurses. *E.g.,* 49 Pa. Code §18.6 (1992) (nurse-midwives); *id.* §18.21 (certified registered nurse practitioners); *id.* §18.141 (physician assistants); *id.* §21.145 (licensed practical nurses). We use the term "nurse" here to refer to the "registered nurse," as defined by 63 Pa. Cons. Stat. Ann. § 213 (Purdon Supp. 1991) and 49 Pa. Code §§ 21.1 and 21.11 (1992).

[13] The Pennsylvania Nursing Law explicitly excludes from the "practice of professional nursing" "acts of medical diagnosis or prescription of medical therapeutic or corrective measures, except as authorized by rules and regulations jointly promulgated by the State Board of Medicine and the [State Board of Nursing]." 63 Pa. Cons. Stat. Ann. § 212 (1); *accord* 49 Pa. Code § 21.1. Specialized nurses, like the "certified registered nurse practitioner," may "perform acts of medical diagnosis or prescription of medical therapeutic or corrective measures,"

are not required to undergo the rigorous medical training necessary to become a licensed physician.[14] As such, we do not believe "the rule of *Incollingo* or its rationale" extends to nurses. *See Coyle,* 584 A.2d at 1386.

To be sure, as the district court observed, nurses often perform tasks "similar to" those performed by physicians, and are therefore more like physicians than are pharmacists. *See Mazur I,* 742 F. Supp. at 255. But these tasks are typically performed under the supervision of, or in collaboration with, physicians. For instance, registered nurses may administer drugs to a patient, but only those "ordered for that patient by a licensed doctor." 49 Pa. Code § 21.14 (1992). Likewise, immunization is a "proper

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but only "in collaboration with and under the direction of a physician licensed to practice in [Pennsylvania]." *Id.* § 21.251.

[14] *Compare* 49 Pa. Code § 17.1 (requirements for license without restriction for medical doctors) *with id.* §§ 21.21–.23 (requirements for license for certified registered nurses).

function" of the registered nurse, but only if "[a] written order has been issued by a licensed physician," and "[t]he policies and procedures under which the registered nurse may administer immunizing agents . . . have been established by a committee representing the nurses, the physicians and the administration of the agency or institution." *Id.* § 21.16.

At bottom it is the physician who is required to make the individualized medical judgment of what treatment to administer in a given instance, and it is the physician who is ultimately held accountable for that decision.[15] Thus, in the distribution system for

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[15] As the District Court noted, 42 Pa. Cons. Stat. Ann. § 8334(a) (1982) extends a limited grant of immunity from liability to *both* physicians and nurses who administer vaccines in the mass immunization context. Although this provision may be further evidence that physicians and nurses act alike in certain respects, we do not find it dispositive of the issue whether nurses may be learned intermediaries under Pennsylvania law.

prescription drugs warnings are directed to physicians and not nurses or pharmacists. "[I]nformation about the risks of medicines is provided to the person who most needs and can best evaluate it–the physician–to be shared with and explained to the patient in the context of his or her individual medical circumstances." *Coyle*, 584 A.2d at 1386.

Accordingly, we do not believe the Pennsylvania Supreme Court would extend the learned intermediary rule

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As we have noted, courts have formulated different liability rules in the mass immunization context. *See Davis v. Wyeth Lab., Inc.*, 399 F.2d at 131. The principal reason for the so–called mass immunization exception to the learned intermediary rule is that when vaccines are administered under "clinic–like" conditions, it is difficult, if not impossible, to render the type of individualized medical care required of the learned intermediary. *See id.* Therefore, although 42 Pa. Cons. Stat. Ann § 8334(a) may be evidence that nurses act like physicians in the mass immunization context, we doubt it reflects a legislative judgment that nurses act like *learned intermediaries* in the mass immunization context. Of course, it remains to be seen whether the immunization program here is within the mass immunization exception. We examine this issue *infra* Part II(C).

to nurses. But even assuming there are circumstances in which a nurse may act as a learned intermediary under Pennsylvania law, we do not think it can be said, as a matter of law, that Nurse Frederick acted as a learned intermediary under the facts here.[16]

The district court found that, based on the "totality of her qualifications and what she did, it is clear that Nurse Frederick was acting as [a] learned intermediary at the time of Lisa's inoculation." *Mazur II,* 767 F. Supp. at 711. It explained:

> Nurse Frederick had the required general education, experience, and authority. She had specialized knowledge concerning the proposed treatment to be administered. She had read the Important Information Statement on at least two occasions before the vaccines were administered. She had particularized understanding of measles, mumps, and

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[16] Merck asserts that Dr. Sharrar acted as a learned intermediary as well. For the reasons articulated by the district court, *see Mazur I,* 742 F. Supp. at 253–54, we find this argument untenable. Therefore, we limit our analysis to the question whether Nurse Frederick acted as a learned intermediary.

> rubella; their symptoms and complications; and the vaccines intended to prevent them. She knew of the more common side effects of those vaccines. Specifically, she was aware that encephalitis could follow the measles virus and the measles vaccine. . . . She was an experienced medical professional with specific training as to the vaccine in question. In sum her knowledge of the "palliative" was sufficient. She was knowledgeable as to health issues of school-age children. Parents relied upon her expertise to aid them when they had questions concerning the school health programs and their child's needs. She reviewed the records of the children at the Morrison school and made individualized decisions concerning each of them. On February 26, 1982, Nurse Frederick checked the students, including Lisa, for visible signs of illness. Ultimately, Nurse Frederick "made a considered medical judgement," and permitted Lisa to receive her MMR II vaccine.

Id. (citations omitted). We disagree.

Although Nurse Frederick is unquestionably qualified as a registered nurse, we cannot agree that she possesses the minimum qualifications and experience required of the learned intermediary. Nurse Frederick stated herself that the "emphasis" of her formal education was on "education" rather than "nursing." As part of her training to become a registered nurse, she learned how to

administer vaccines. But although Nurse Frederick had some classes in medication, she was never trained in weighing the risks and benefits of vaccination in a given instance. In 1980 Nurse Frederick attended a one-year, nurse practitioner program at the University of Pennsylvania. But this program centered on physical examinations of children, and did not include detailed instruction on immunization or pediatric diseases.

Although Nurse Frederick is experienced in administering and dispensing drugs, she is not authorized to prescribe drugs. When Nurse Frederick dispensed drugs as part of a pediatric course she took at Philadelphia General Hospital, she did so only pursuant to "doctor's orders." As a school nurse, Nurse Frederick may only dispense Tylenol to children.

Nurse Frederick is capable of describing the symptoms of measles, and is aware that various side effects and complications can result from inoculation with measles,

mumps, and rubella vaccines. However, at the time Lisa Mazur was vaccinated, Nurse Frederick was unaware that SSPE is a possible complication of measles vaccine. Moreover, as the district court noted, Nurse Frederick was unable to 'state how a virus travels through the body, how a virus causes illness, or how a vaccine prevents illness." *Mazur II,* 767 F. Supp. at 709. Likewise, although she was aware that children running fevers should not be vaccinated. Nurse Frederick was unable to explain why, and said that in such a case she would refer the child to a physician.

Nurse Frederick's only knowledge of the MMR II vaccine was obtained from her participation in the city's immunization program, and in particular, the Important Information Statement, which she reviewed at least twice. Nurse Frederick does not remember reading the package circular, though she was aware that it came with each vial of MMR II vaccine. Moreover, although she had "access" to vials of MMR II vaccine on the day it was administered

to students at the Morrison School, Nurse Frederick said that the "vaccines were not in her hands" and "were entirely managed by the Department of Health Technician."[17]

Accordingly, we do not believe Nurse Frederick possessed the cumulative medical knowledge and experience necessary to make an individualized judgment as to which students should have been vaccinated on February 26, 1982, let alone to recognize the "characteristics" of the MMR II vaccine, determine "the amount of the drug which [could] be safely administered" and assess "the different medications the patient is taking." *See Makripodis,* 523

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[17] We agree with the district court that, for purposes of determining whether Merck met its duty to warn by providing an adequate warning to a learned intermediary, it is immaterial whether Nurse Frederick actually read the package circular so long as it was made available to her. *Mazur II,* 767 F. Supp. at 712–13. However, the fact that Nurse Frederick may have never reviewed the package circular is relevant to the determination whether she acted as a learned intermediary on the day Lisa Mazur was inoculated, and we must assume at this stage that Nurse Frederick was not familiar with the package circular's contents.

A.2d at 378. Nor do we think she acted like a learned intermediary that day.

Although Nurse Frederick virtually ran the immunization program at the Morrison School, our focus here is on how she acted the day Lisa Mazur was inoculated. As we have noted, Nurse Frederick took each student's permission form, checked it against her health records, and informed the technician which vaccine to administer. In addition to cross-checking records, Nurse Frederick said that "one of [her] jobs . . . [was] to be kind of eyeballing the boys and girls to see whether they looked ill that day or if there was some reason they should not get the vaccine." She elaborated that, as students passed by her, she examined their "overall appearance," looking for "obvious things" such as signs of lethargy, runny eyes and noses, coughing and sneezing, and, sometimes, asked them how they felt or put her arm around them. Nurse Frederick did not ask students whether they were on medication that

day, and does not remember whether she turned any students away because of their "overall appearance."

As the Court of Appeals observed in *Reyes v. Wyeth Laboratories,* the "choice . . . [of the learned intermediary] is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative." 498 F.2d at 1276. Nurse Frederick had sufficient knowledge of neither patient nor palliative. As a result, she was incapable of rendering an individualized medical judgment as to which students should be vaccinated. This is not to say that Nurse Frederick did not perform her job on the day Lisa Mazur was inoculated, only that she did not act as a learned intermediary between Merck and vaccinees.

Accordingly, we cannot agree, as a matter of law, that Nurse Frederick acted as a learned intermediary on the facts here.[18] Because we conclude that Nurse Frederick

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[18] The cases in which courts in other jurisdictions have extended the learned intermediary rule to nurses are not to

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the contrary. *See* text accompanying *supra* note 10. In *Rohrbough v. Wyeth Laboratories, Inc.* the district court applied the learned intermediary rule to a nurse who administered a vaccination to the plaintiff in a public health clinic. The court noted that the plaintiff "did not receive [her vaccination] as a part of a mass vaccination program but after talking with the Registered Nurse who ultimately

(footnote no. 18 continued...)

made a considered medical judgment and administered the shot." 719 F. Supp. at 478. Moreover, the plaintiff in that case neither contended that the nurse was not "sufficiently experienced to be a 'learned intermediary'" nor argued that "she was not apprised of the risks associated with the . . . vaccine. *Id.*

In *Walker v. Merck & Co.* the district court held that the learned intermediary exception applied to nurses under Georgia law. That case involved the administration of the MMR II vaccine to a pregnant high school student as part of a county-wide immunization program similar to Philadelphia's program here. The plaintiff "received [her] MMR II injection from a licensed practical nurse who was aware of the risks associated with MMR II, particularly the risks for pregnant females, and who stated that she had read and understood the circular accompanying the MMR II." 648 F. Supp. at 934. In addition, the nurse who administered the vaccine, who had experience as a licensed practical nurse but no specialized training in vaccination, "stated unequivocally" that before she administered the vaccine to the plaintiff she explicitly asked her whether she was sexually active and whether there was a possibility she

was not a learned intermediary, we do not address at this point whether the package circular constituted an adequate warning.[19] Instead, we must next determine whether

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was pregnant. *Id.* at 933.

In finding the learned intermediary rule applicable, the *Walker* court relied squarely on a Georgia Court of Appeals decision, *Singleton v. Airco, Inc.*, 314 S.E.2d 680 (Ga. App. 1984), which extended the learned intermediary rule to nurses under Georgia law. The plaintiff in *Singleton* (footnote no. 18 continued...)

died after developing malignant hyperthermia, a known adverse effect of an anesthetizing agent manufactured by the defendant. The court found the "drug insert warnings adequate for the use of a professional trained in the administration of anesthesia, and that the [defendant was] not in any way responsible for [the plaintiff's] death." *Id.* at 682. Significantly, the nurse who administered the anesthesia to the plaintiff had written a paper on malignant hyperthermia while she was studying to become an anesthesiologist, and "was familiar with the drug inserts and stated that she made a hobby of collecting this information while she was a student." *Id. See also Holley v. Burroughs Wellcome Co.,* 330 S.E.2d 228 (N.C. App. 1985) (extending learned intermediary rule to nurse/anesthesiologist under similar facts), *aff'd,* 348 S.E.2d 772 (N.C. 1986).

[19] As we have noted, to meet its duty to warn under the learned intermediary rule, a prescription drug manufacturer must provide an adequate warning to a

Merck was obligated to warn users of the risks of its MMR II vaccine directly under the mass immunization exception to the learned intermediary rule.

C.

Although it determined that Nurse Frederick was a learned intermediary, the district court assumed, for purposes of argument, that she was not and went on to consider whether the mass immunization exception is applicable here. It found that exception inapplicable, because "there was no evidence Merck foresaw that no

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learned intermediary. *Incollingo v. Ewing,* 282 A.2d at 220. Because we conclude, as a matter of law, that Nurse Frederick did not act as a learned intermediary under the facts here, it is not necessary to decide whether the package circular constitutes and adequate warning. We address the adequacy of the package circular *infra* Part II(D), however,

(footnote no. 19 continued...)

in determining whether Merck satisfied its duty to warn by contractually obligating the CDC to warn users directly.

learned intermediary would be present at inoculation, the Health Department program was not large enough to be a mass immunization program, and the vaccine was not dispensed to "all-comers." *Mazur I,* 742 F. Supp. at 257. We disagree.

As we have discussed, where vaccine is not dispensed on the basis of an individualized medical judgment but to "all comers at mass clinics," courts in other jurisdictions have held that "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself, or by obligating the purchaser to give warning." *Davis v. Wyeth Lab., Inc.,* 399 F.2d at 131. The Pennsylvania Supreme Court has yet to address the applicability of this so-called mass immunization exception under Pennsylvania law. However, we assume, for purposes of our analysis here, that it would

adopt the reasoning of the mass immunization cases under the appropriate circumstances.[20]

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[20] The Pennsylvania Supreme Court has yet to be presented with a situation where the mass immunization exception would apply. However, it has adhered to the

(footnote no. 20 continued...)

"rule of *Incollingo* [and] its rationale," *Coyle*, 584 A.2d at 1386, the mass immunization exception has been accepted in other jurisdictions, and there is no contrary authority under Pennsylvania law.

In *Taurino v. Ellen*, 579 A.2d 295 (Pa. Super. 1990), the Pennsylvania Superior Court held that the manufacturer of Loestrin, an oral contraceptive, was not liable for failing to warn users directly where that drug was dispensed at a women's clinic by an employee who was not a physician. However, this holding was premised on the assumption that the "manufacturer ha[d] no reason to know that this w[ould] occur," *Id.* at 928, and, as we discuss above, the applicability of the mass immunization exception turns on the *foreseeability* that a vaccine will be dispensed without a learned intermediary present. Therefore, *Taurino* is inapposite.

In any event, because we conclude *infra* Part II(D) that Merck satisfied any duty it had to warn users directly by contractually obligating the CDC to warn vaccinees of the risks of its MMR II vaccine, we need not decide the applicability of the mass immunization exception under Pennsylvania law.

As we have noted, the mass immunization exception is better thought of as one context where a prescription drug manufacturer is obligated to warn users directly of the facts which make its product dangerous. That is, it restores the prescription drug manufacturer's duty to warn users directly, which is satisfied indirectly where the prescription drug manufacturer provides an adequate warning to a learned intermediary, because the rationale supporting the learned intermediary rule buckles where prescription drugs are dispensed without an individualized medical balancing of the risks and benefits to the user. The seminal cases on the mass immunization exception to the learned intermediary rule, *Davis v. Wyeth Laboratories, Inc.* and *Reyes v. Wyeth Laboratories*, are instructive.

In *Davis* the plaintiff contracted polio after being vaccinated for that disease as part of a nationally sponsored immunization program, and sued the manufacturer of the vaccine for, among other things, failure to provide an

adequate warning. The jury returned a verdict for the defendant, but the court of appeals reversed on the ground that "the manufacturer [had] a duty to warn the consumer (or make adequate provision for his being warned) as to the risks involved." 399 F.2d at 130.

The *Davis* court explained:

> Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer without a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient.

Here, however, *although the drug was denominated a prescription drug it was not dispensed as such. It was dispensed to all comers at mass clinics without an individualized balancing by a physician of the risks involved. In such cases . . . warning by the manufacturer*

to its immediate purchase will not suffice. The decision (that on balance and in the public interest the personal risk to the individual was worth taking) may well have been that of the medical society and not that of [the manufacturer]. But just as the responsibility for choice is not one that the manufacturer can assume for all comers, neither is it one that he can allow his immediate purchaser to assume. *In such cases, then, it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or obligating the purchaser to give warning.* *Id.* at 130–31. (emphasis added).

In *Reyes* the Court of Appeals adopted the reasoning of *Davis* on similar facts. The plaintiff in that case contracted polio slightly more than two weeks after she was vaccinated for that disease at a county health clinic. The vaccine was administered by a registered nurse; no physician was present. The nurse who administered the vaccine said that she read the package circular

accompanying the vaccine, but did not warn the plaintiff of the risks of vaccination.

The plaintiff sued the manufacturer of the vaccine for, among other things, failure to warn. The defendant argued that it met its duty to warn by inserting an adequate warning – the package circular – in the vials of vaccine, and that *Davis* was distinguishable because (1) whereas the plaintiff in *Davis* was vaccinated as part of a mass immunization program, the plaintiff in *Reyes* was vaccinated at her parents' request; (2) whereas the plaintiff in *Davis* was vaccinated by a pharmacist, the plaintiff in *Reyes* was vaccinated by a "public health nurse"; (3) compared to the defendant in *Davis*, it "played a relatively passive role" in the national immunization program; and (4) unlike the defendant in *Davis*, it "had no knowledge that the vaccine would not be administered as a prescription drug." 498 F.2d at 1277.

The *Reyes* court found the defendant's arguments unpersuasive. Embracing the rationale of *Davis*, the court first observed that "[w]here there is no physician to make an 'individualized balancing . . . of the risks,' . . . the very justification for the [learned intermediary rule] evaporates." *Id.* at 1276 (quoting *Davis*, 399 F.2d at 131). The court then rejected the defendant's attempt to distinguish *Davis* on the facts presented.

> None of the asserted grounds for distinguishing *Davis* justifies a different result here. The first two arguments are admittedly distinctions between *Davis* and the instant controversy, but they have no bearing on the rationale of the *Davis* opinion. ***Whether vaccine was received during a mass immunization program or an on-going program whether it was administered by nurse or pharmacist, it was, in both cases, dispensed without the sort of unindividualized medical balancing of the risks to the vaccinee that is contemplated by the prescription drug exception.***

The third and fourth asserted reasons for distinguishing *Davis* from this case are essentially the same: [the defendant] took no active part in the vaccination

process here, and did not know that its vaccine would be dispensed without procedures appropriate for distribution of prescription drugs. Were we to conclude that [the defendant] neither knew nor had reason to know that its vaccine would be dispensed without prescription drug safeguards, we might be able to hold that the *rationale* in *Davis* is inapplicable here. But [the defendant] had ample reason to foresee the way in which its vaccine would be distributed. *Id.* at 1277 (emphasis added). The Court concluded that the defendant "was required to warn foreseeable users, or see that the Texas Department of Health[21] warned them." *Id.*

As *Davis*, and particularly *Reyes,* suggest, it is not the size of the immunization program which dictates whether the mass immunization exception is applicable, but

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[21] Like the CDC here, the Texas Department of Health had purchased the polio vaccine from the defendant in *Reyes*, and shipped it to county health authorities for distribution. 498 F.2d at 1270.

rather whether the vaccine was dispensed without an individualized medical balancing of the risks and benefits of inoculation and the foreseeability that the vaccine would be dispensed in this manner.[22] The scope of the immunization program is, of course, relevant to the determination whether it is foreseeable that a vaccine will be dispensed under "clinic-like" conditions, but it is not controlling. Therefore, we cannot agree that the size of the city's immunization program alone, which initially involved a pool of some 300,000 potential vaccinees city-wide,

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[22] The cased cited by the district court in which courts have construed the mass immunization exception narrowly are not to the contrary. *See Mazur I,* 742 F.2d at 255. As we have noted, in *Walker v. Merck & Co.,* 648 F. Supp. at 934, the district court found that the nurse who administered the vaccine was a learned intermediary. Therefore, it follows that the mass immunization exception was not applicable. *See supra* note 18. Likewise, in *Petty v. United States,* 740 F.2d at 1440 (emphasis added), the court of appeals opined: "The duty to warn is imposed on the manufacturer and in a mass-immunization context, *where there is no learned intermediary,* the duty extends to the ultimate recipient of the vaccine."

precludes the application of the mass immunization exception here.

We have already determined that the MMR II was not dispensed by a learned intermediary on the day Lisa Mazur was inoculated. Students were led into the gymnasium at the Morrison School and vaccinated in "assembly line" fashion; no individualized medical judgment was rendered as to which students should be vaccinated that day.[23] *Cf. Hurley v. Lederle Lab.*, 863

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[23] Merck argues that the mass immunization exception is inapplicable, because about two-thirds of the 300,000 students originally eligible for the city's immunization program had ben weeded out by the time the MMR II vaccine was actually administered. However, as the Mazurs point out, these students were excused largely on the basis of an administrative process of elimination. That is, the vast majority of these students were eliminated because of medical records revealing that they had already been

(footnote no. 23 continued...)

vaccinated. With respect to the remaining 100,000 students, or at least those who attended the Morrison School, there was no individualized medical judgment made as to who should be inoculated. Our focus here is on these students.

F.2d 1173 (5th Cir. 1988).[24] Therefore, the pertinent inquiry here is whether Merck knew or had reason to know that its vaccine would be dispensed in this manner.

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[24] In *Hurley* the recipient of a whooping cough vaccine and his parents sued the manufacturer of the vaccine for, among other things, failure to provide an adequate warning. The plaintiffs contended that the vaccine was administered in "a 'clinic-like' atmosphere," and that the mass immunization exception was thus applicable. 863 F.2d at 1178. The Court of Appeals disagreed:

> We are convinced . . . the . . . mass immunization exception . . . is not applicable. Unlike *Reyes*, here the child's personal physician prescribed the shot, and the vaccine was administered under the supervision of the physician in his office by his nurse. In short, *there is no question whatsoever but that a patient-physician relationship existed before and at the time the immunization was given.* Indeed, Dr. Lanier testified that he had actually examined the child. Moreover, the Hurleys admitted in their complaint that the vaccine was administered under the direction and control of Dr. Lanier.

Id. (emphasis added). By contrast, no patient-physician relationship ever existed as to Lisa Mazur at the Morrison School and no physician was present on the day she was inoculated.

Prescription drug manufacturers are charged with knowledge of the distribution system in which their products are sold. As the *Reyes* court noted:

> A drug manufacturer is held to the skill of an expert in his field, and is presumed to possess an expert's knowledge of the arts, materials, and processes of the pharmaceutical business. Included in such expertise must be a familiarity with practices and knowledge common in the drug industry as to distribution and administration of pharmaceutical products.

498 F.2d at 1277 (footnote omitted). *See also Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132, 146 (3d Cir. 1973) (noting that under Pennsylvania law drug manufacturers "must be charged with knowledge of the workings of the distribution system by which they chose to state the dangerous effects of [drugs they manufacture] and the short-comings therein").

Merck sold its MMR II vaccine to the CDC for use by state and local health agencies. Although Merck contractually obligated the CDC to warn users directly, it

did not require it to ensure that a learned intermediary would be present. Rather, it gave the CDC the option of seeing that its MMR II vaccine was administered by a physician or providing meaningful warnings to vaccinees. From the beginning, it was apparent that the CDC intended to comply with the duty to warn provision of its purchase contract with merck by developing the Important Information Statement. The CDC made no attempt to ensure that the MMR II vaccine was administered by a learned intermediary. Indeed, as we have noted, although health care professionals like Nurse Frederick had access to the package circular, no provision was made by either the CDC or Merck to see that they read them. Therefore, we cannot agree, as a matter of law, that there was no reason for Merck to foresee that its MMR II vaccine would be dispensed without an individualized medical balancing of the risks and benefits of inoculation.

Because we believe the MMR II vaccine was dispensed under "clinic-like" conditions on the day Lisa Mazur was inoculated and it was foreseeable that the vaccine would be dispensed in this manner, we conclude that the mass immunization exception is applicable here, thus obligating Merck to warn users of the risks of its vaccine directly. The only question remaining is whether Merck satisfied its duty to warn, as a matter of law, by contractually obligating the CDC to see that its MMR II vaccine was administered by a physician or to provide meaningful warnings to vaccinees.

D.

According to the district court, "Merck is not responsible for Lisa's injuries if it acted reasonably when it contracted with the CDC and relied upon its guarantee that the MMR II vaccine would be administered by a physician or after a meaningful warning had been provided to Lisa or

her parents." *Mazur II,* 767 F. Supp. at 701. Because it found that Merck reasonably relied on the CDC to draft the Important Information Statement and disseminate it to vaccinees, the district court held that "Merck exercised reasonable care to be sure the Mazurs were informed directly of the risks of MMR II vaccinations. *Id.* at 708. We agree.

As we have discussed, in *Davis v. Wyeth Laboratories, Inc.* the Court of Appeals held that, in the mass immunization context, "it is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning." 399 F.2d at 131. *Accord Reyes v. Wyeth Lab.,* 498 F.2d at 1276 (holding that, where no learned intermediary is present, "the manufacturer is required to warn the ultimate consumer, or to see that he is warned"). Although it is clear Merck itself made no effort to warn vaccinees directly, it did contractually obligate the

CDC to do so. Therefore, we must determine whether a vaccine manufacturer may meet its duty to warn under Pennsylvania law by obligating the CDC to warn users directly where the learned intermediary rule in inapplicable.

As the district court observed, in *Berkebile v. Brantly Helicopter Corp.*, 337 A.2d 893, 903 (Pa. 1975), a plurality of the Pennsylvania Supreme Court stated that "[t]he duty to provide a non-defective product is non-delegable," and, as we have noted, an inadequate warning renders a product defective. Relying on *Berkebile,* the Mazurs argue that Merck cannot "delegate"[25] its duty to warn under Pennsylvania law to the CDC by contractually obligating it to warn users directly. We disagree.

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[25] The District Court drew a distinction between "delegating" one's duty to warn and "assigning" it. *See Mazur I,* 742 F. Supp. at 260 n.28. Because we believe *Berkebile* is inapposite for the reasons we express above, we find it unnecessary to explore the difference between the delegation and assignment of duties under Pennsylvania law.

Berkebile is first, and foremost, a section 402A case, and is inapposite here.

The plaintiff in *Berkebile*, the wife/executrix of a man killed in a helicopter crash, brought suit against the manufacturer of the helicopter under section 402A of the *Restatement (Second) of Torts* alleging, among other things, failure to warn. In discussing the defendant's duty to warn, the Supreme Court distinguished between the manufacturer's duty to warn in negligence, which is governed by the "reasonable man standard," 337 A.2d at 902 (citing *Thomas v. Arvon Prods. Co.*, 227 A.2d 897 (Pa. 1967)), and the manufacturer's duty to warn in strict liability which is "to provide [adequate] warnings in a form that will reach the ultimate consumer and inform of the risks and inherent limits of the product," *id.* at 903.

As we have explained, although the Mazurs' failure to warn claims were founded in both negligence and strict liability, Merck's duty to warn is governed by section 388

of the *Restatement* because the MMR II vaccine is an "unavoidably unsafe product." Under that section, Merck has a duty "to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Incollingo v. Ewing,* 282 A.2d at 220 n.8. The commentary to section 388 recognizes that, in certain instances, a manufacturer may meet its duty to warn by entrusting the communication of warnings to third persons.

Comment *l* to section 388 provides:

> The supplier's duty is to exercise reasonable care to inform those for whose use the article is supplied of dangers which are peculiarly within his knowledge. *If he has done so, he is not subject to liability, even though the information never reaches those for whose use the chattel is supplied.* The factors which determine whether the supplier exercises reasonable care by giving this information to *third persons* through whom the chattel is supplied for the use of others, are stated in Comment n.

Restatement (Second) of Torts §388 cmt. *l*(emphasis added).

Comment n to section 388 provides in part:

> Giving to the third person through whom the chattel is supplied all the information necessary to its safe use is not in all cases sufficient to relieve the supplier from liability. It is merely a means by which this information is to be conveyed to those who are to use the chattel. . . . [I]t is obviously impossible to state in advance any set of rules which will automatically determine in all cases whether one supplying a chattel for the use of others through a third person has satisfied his duty to those who are to use the chattel by informing the third person of the dangerous character of the chattel, or of the precautions which must be exercised in using it in order to make its use safe. There are, however, certain factors which are important in determining this question. *There is necessarily some chance that information given to the third person will not be communicated by him to those who are to use the chattel. This chance varies with the circumstances existing at the time the chattel is turned over to the third person, or permission is given to him to allow others to use it.* These circumstances include the known and knowable character of the third person and may also include the purpose for which the chattel is given. . . .[T]he care which must be taken always increases with the danger involved. . . .

Id. §388 cmt. n (emphasis added).

Accordingly, we believe a vaccine manufacturer may satisfy its duty to warn in the mass immunization context by obligating the CDC to warn users directly if it informs that agency of the facts which make its vaccine dangerous and reasonably relies on it to communicate such information to users in lay terms. *But cf. Petty v. United States,* 740 F.2d 1428 (8th Cir. 1984).[26] The

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[26] In *Petty* the plaintiff filed suit against the federal government in negligence and strict liability for, among other things, failure to warn of the risks of a swine flu vaccination he received. The District Court found the government liable under Iowa law, and the Court of Appellees affirmed. Among other things, the *Petty* court rejected the government's argument that it statutorily assumed the vaccine manufacturer's (Merrill–National) duty to warn users directly:

> We recognize that the government has attempted to statutorily assume the duty to warn the vaccinees, however, we do not find that this delegation thereby relieves the manufacturer from liability for any resulting inadequacy of the warning. The duty to warn is imposed on the manufacturer and in a mass–immunization context, where there is no learned intermediary, the duty extends to the ultimate recipient of the vaccine. Delegation of the duty does not, in itself, relieve the manufacturer of

manufacturer's responsibility is continuous, and it must therefore apprise the CDC of any risks it later discovers or, in the exercise of reasonable care, should have discovered.

> its obligation, nor should it insulate the manufacturer from liability for deficiencies in the manner in which the chosen intermediary effectuates the manufacturer's duty. Although on the side lines, Merrill-National is assumed to have had the knowledge of the warning issued and to have had the ability to affect the warning.

740 F.2d at 1440. Because the Court found the government's warning, disseminated in the form of an Important Information Statement, inadequate, it held that

(footnote no. 26 continued...)

Merrill-National was strictly liable for failure to warn under Iowa products liability law. *Id.* at 1441.

Significantly, Iowa law adheres to a formal product/conduct distinction in evaluating failure to warn claims founded in negligence and strict liability. *Id.* at 1440; *see supra* note 8. Accordingly, the *Petty* court formulated Merrill-National's duty to warn under Section 402A of the *Restatement (Second) of Torts*. As we have discussed, in the prescription drug context, the Pennsylvania Supreme Court law applies the Section 388 duty to warn regardless whether the plaintiff's failure to warn claim is founded in negligence or strict liability. Therefore, *Petty* is inapposite.

The question whether a vaccine manufacturer reasonably relied on the CDC to warn users directly turns on the foreseeability that vaccinees will not be adequately warned. Because the uninformed use of vaccines can be life-threatening, vaccine manufacturers must be held to a high standard of care where they choose to obligate the CDC to warn users directly.[27]

All that remains to be decided is whether Merck satisfied its duty to warn, as a matter of law, under the facts here. To answer this question, we must first determine whether Merck properly informed the CDC of the facts which make its MMR II vaccine dangerous. We focus here on the adequacy of the package circular contained in each vial of MMR II vaccine shipped to the CDC for distribution

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[27] Our analysis here is limited to the situation where a vaccine manufacturer obligates the CDC to warn users directly. We need not address whether it would be reasonable for a vaccine manufacturer to rely on another supplier.

in the public health sector.[28] Our inquiry is guided by the traditional tort analysis of adequacy of warning.

Under Pennsylvania law the determination whether a warning is adequate is a question of law. *Mackowick v. Westinghouse Elec. Corp.*, 575 A.2d 100, 102 (Pa. 1990). Adequacy of warnings "should be considered with a view to all the evidence." *Berkebile*, 337 A.2d at 902. Adequacy of warnings is determined on the basis of the information that was known or knowable at the time the cause of action accrued. *Leibowitz v. Ortho Pharmaceutical Corp.*, 307 A.2d 449, 458 (Pa. Super. 1973). Warnings that meet federal drug labeling requirements are afforded some deference. *White v. Weiner*, 562 A.2d at 383.

In *Mazur I*, the district court determined that the package circular was adequate in all respects except for the

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[28] By focusing on the package circular, we do not suggest that there are not other ways in which a vaccine manufacturer might inform the CDC of the facts which make its vaccine dangerous.

revaccination statement. Because that "statement provide[d] no information about the potential risks associated with revaccination," the Court found that there was a genuine issue of material fact as to the adequacy of the package circular's warning. 742 F. Supp. at 258. In *Mazur II,* however, the Court concluded that the package circular, and, in particular, its revaccination paragraph, was adequate as a matter of law based on the state of medical knowledge in 1982, the year Lisa Mazur was inoculated. 767 F. Supp. at 713. We agree with the district court for the reasons it expressed.

We limit our discussion here to the Mazur's novel challenges to the adequacy of the package circular on appeal. They contend that the package circular improperly recommends the use of the MMR II vaccine for those over the age of eight years, despite the lack of clinical studies establishing that the vaccine could be safely administered to "adults." However, as Merck notes, the Mazurs have not

pointed to any scientific evidence (available in 1982 or since then) in the record indicating that the MMR II vaccine poses a greater risk to adults than children.

The Mazurs further assert that the package circular is inadequate because it only contraindicates the administration of the MMR II vaccine for those "receiving" corticosteroids as opposed to those who "recently received" them.[29] But we think it sufficient that the package circular provided that "patients receiving therapy with . . . corticosteroids" should not be vaccinated. The package circular's intended audience is not the ultimate user, but rather the learned intermediary. *See Mackowick*, 575 A.2d

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[29] In the six-month period leading up to her inoculation, Lisa Mazur suffered from pharyngitis, for which she was treated with the corticosteroid Depo-Medrol and eventually had her tonsils removed. On February 26, 1982, Lisa was no longer being treated with corticosteroids. But the Mazurs maintain she was still in an "immuno-suppressed condition," because of the "long half-life" of Depo-Medrol, and therefore should have been warned of the heightened risk of vaccination caused by her recent corticosteroid use.

at 102 ("[W]arnings must be directed to the understanding of the intended user."). Here the package circular was directed to the CDC, who was contractually obligated to develop a meaningful warning for vaccinees or their parents.

Finally, the Mazurs argue that the package circular is inadequate because it give a "self-serving and overly-technical explanation" of the risk of contracting SSPE from the MMR II vaccine. As Merck points out, however, that portion of the package circular pertaining to the risk of contracting SSPE was taken, almost verbatim, from a 1977 government report on the association between naturally occurring measles, measles vaccine, and SSPE. Moreover, as we have noted, the package circular's intended audience here is the CDC, who Merck contractually obligated to develop a warning in lay terms.

Accordingly, we believe Merck adequately informed the CDC of the facts which make its MMR II vaccine

dangerous. The second question is whether Merck reasonably relied on the CDC to communicate this information to vaccinees directly. The focus here is on the foreseeability that the CDC would not honor its purchase contract with Merck, which required it to see that the MMR II vaccine was administered by a physician or to provide meaningful warnings to vaccinees. For purposes of this inquiry, we assume, as we must at this stage, that Mrs. Mazur never received the Important Information Statement.

As we have noted, from the beginning it was apparent that the CDC intended to meet its contractual obligation to warn MMR II vaccinees directly by providing a meaningful warning to vaccinees rather than ensuring that the vaccine was administered by a physician. The CDC developed this warning–the Important Information Statement–based on Merck's package circular, previous studies it had conducted, and its expertise in the field of

vaccine safety and administration.[30] The district court concluded that Merck reasonably relied on the CDC to develop the Important Information Statement and disseminate it to vaccinees. *Mazur II,* 767 F. Supp. at 704. We agree.

As the district court noted, "Merck initially selected the CDC as the vehicle through which it would provide

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[30] The adequacy of the Important Information Statement is immaterial to our analysis here. In the first place, as we have noted, we must assume Mrs. Mazur never received the Important Information Statement. Therefore, even if it is inadequate, the Important Information Statement could not have been a proximate cause of Lisa's vaccination. *See Mazur I,* 742 F. Supp. at 259–60. More important, our inquiry here is whether Merck reasonably relied on the CDC to honor its contractual obligation by developing a meaningful warning and disseminating it to vaccinees, not whether the CDC in fact developed an adequate warning and successfully disseminated it to vaccinees. The latter inquiry would only be appropriate under strict liability principles, which, for the reasons we have expressed, are not controlling here. This is not to say, however, that the Important Information Statement is altogether irrelevant for purposes of determining whether Merck reasonably relied on the CDC. As the District Court observed, its contents may inform our reasonableness analysis in certain respects. *See Mazur II,* 767 F. Supps. at 705 n.13.

adequate warnings to consumers because the CDC sold the vaccine to the state and local health organizations, supervised the distribution of vaccines, and had vastly more experience than Merck did in the public health field." *Id.* at 708. Given the resources and funding available to the CDC, as well as its expertise in immunology and public vaccination, we believe Merck's decision to rely on the CDC to warn users directly was reasonable.

As the district court observed:

> The CDC is an agency of the Public Health Service of the United States Department of Health and Human Services. It is empowered to conduct studies, evaluations, tests, and emergency programs in order to prevent the spread of disease and to improve public welfare. With respect to vaccines, it plays a vital role in research, development, testing, and distribution. It publishes the *Morbidity and Mortality Weekly Report,* among other reports, studies, and journals to educate public health and medical professionals about the risks and benefits of immunization.

Id. at 706 (citations omitted).

The CDC is also affiliated with the Immunization Practices Advisory Committee, which is responsible for

recommending the use of vaccines in the public health sector and comprises representatives from the American Medical Association, the American Academy of Pediatrics, the American College of Physicians, the American Academy of Family Practices, the Department of Defense, the Bureau of Biologics, the National Institutes of Health, and the Canadian National Advisory Committee on Immunization.

Furthermore, Merck carefully researched the CDC before it agreed to sell its MMR II vaccine to the CDC for use in the public health sector. As the district court stated, "Merck based its decision [to rely on the CDC to warn users directly] on its own past experience with the CDC; recommendations from physicians; the Bureau of Biologics, consumer groups; and on conversations with the CDC." 767 F. Supp. at 708. And once Merck made its decision to rely on the CDC,

> It monitored the CDC's performance through conversations with these same individuals and others. . . .[E]ach one of these sources told [it]. . . that consent forms and Important Information Statements were being sent by the CDC and, in turn, to parents by local health organizations participating in CDC immunization programs. . . . Through its regular contact with these sources Merck continually checked the CDC's dissemination efforts. At no time did it appear the CDC was not doing its job.

Id.

Perhaps, as the district court noted, "Merck might have been more thorough in its examination [of the CDC]." It could have, for example, "hired an independent contractor to review the CDC's conduct." *Id.* But we are satisfied that Merck reasonably relied on the CDC to warn vaccinees directly on the facts before us, and therefore agree with the district court that "Merck . . .could not have foreseen that Mrs. Mazur would not receive an Important Information

Statement." *Id. Cf. Walker v. Merck & Co.*, 648 F. Supp. at 935.[31]

Accordingly, we cannot accept the Mazurs' contention that it was foreseeable that the CDC would "down play" the risks of inoculation with the MMR II vaccine. There is nothing in the record suggesting that the CDC understand the risks of vaccination.[32] Likewise, we

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[31] In *Walker* the District Court held that Merck satisfied its duty to warn, as a matter of law, by entering into the identical contractual provision with the CDC as that here. The *Walker* court's holding, however, is only dictum because it had already found the learned intermediary rule satisfied. *See supra* note 18. Moreover, as the District Court observed, the *Walker* court's analysis of the Merck–CDC purchase contract was too narrow, because it ignored altogether the issue whether Merck reasonably relied on the CDC to warn vaccinees directly. *Mazur I,* 742 F. Supp. at 261 n.29.

[32] As Merck points out, the Important Information Statement provides in part:

> Although experts are not sure, it seems that very rarely children who get the [measles, mumps, and rubella] vaccines may have a more serious reaction, such as inflammation of the brain (encepalitis), convulsions with fever, or nerve deafness.... With any vaccine or drug, there

cannot agree that Merck's reliance on the CDC to warn vaccinees directly was unreasonable because, given the "practical difficulties of obtaining informed consent from children in a school vaccination clinic setting," it was foreseeable that "some" parents would not receive or heed the Important Information Statement. As we have explained, Merck had a duty to exercise reasonable care to see that vaccinees were informed of the risks of its MMR II vaccine. For the reasons we have expressed, we are satisfied that Merck met this duty.

III.

We conclude that the district court properly granted summary judgment for Merck on the Mazurs' duty to warn claims. Merck's duty to warn is governed by section 388 of the *Restatement (Second) of Torts*. Under that section,

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is a possibility that allergic *or other more common serious reactions or even death could occur*. (emphasis added).

Merck had a duty to exercise reasonable care to inform vaccinees of the facts which make its MMR II vaccine dangerous.

Merck could have satisfied this duty by providing an adequate warning to a learned intermediary. However, Nurse Frederick did not, as a matter of law, act as a learned intermediary between Merck and Lisa Mazur on the facts here. And because it was foreseeable that the MMR II vaccine would be dispensed without an individualized medical judgment of the risks and benefits of inoculation, Merck was obligated to warn users of the risks of its MMR II vaccine directly under the mass immunization exception to the learned intermediary rule.

Nevertheless, Merck met this duty by contractually obligating the CDC to see that its MMR II vaccine was administered by a physician or to provide meaningful warnings to vaccinees. Merck adequately informed the CDC of the facts which make its MMR II vaccine

dangerous, and reasonably relied on the CDC to communicate these risks to vaccinees in lay terms. Accordingly, we hold that Merck satisfied its duty to warn as a matter of law, and we will affirm the district court's order granting summary judgment for Merck.

Lisa Marie Mazur, a Minor, in her own right, and Anthony Mazur and Edna Mazur, as Parents and Guardians, and in their own right

v.

MERCK & CO., INC.

Civ. A. No. 85-6494

United States District Court, E.D. Pennsylvania

June 27, 1991.

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OPINION
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DITTER, District Judge.

In this case, a manufacturer is charged with failing to warn that the use of its vaccine might lead to serious consequences. Before me is the supplemental motion of defendant Merck & Co., Inc. for summary judgment and to

exclude expert testimony.[1] Plaintiffs Lisa Marie Mazur and her parents, Anthony and Edna Mazur, claim that Lisa contracted subacute sclerosing panencephalitis ("SSPE"), a sever, often terminal, illness of the central nervous system, as a result of an inoculation with a measles, mumps, and rubella vaccine ("MMR II") manufactured by Merck.

Merck's first motion for partial summary judgment was denied in part and granted in part. *Mazur v. Merck*, 742 F.Supp. 239, 266 (E.D.Pa. 1990). I denied Merck's

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[1]At oral argument, Merck withdrew that portion of its motion concerning expert testimony and causation. Merck had argued plaintiffs' experts' testimony on the causal relationship between its vaccine and Lisa Mazur's illness was not supported by the medical literature and did not create a genuine issue of material fact as to causation. Merck reserved the right to re-argue that point. Plaintiffs have withdrawn their claims that Merck's vaccine was defectively designed and manufactured. Merck had previously moved for summary judgement on those claims. The motion is moot as to them. Merck also asserted that the Mazurs have not shown and could not prove the proximate cause element of a duty to warn claim. That issue has been fully briefed by the parties. However, I will not express an opinion on that point as it is unnecessary to do so because the motion will be granted on other grounds.

motion as to the federal preemption and statute of limitations issues. *Id.* After a lengthy discussion of the many other matters raised by the parties, I found that additional discovery and briefing was necessary and gave the parties time to conduct both. *Id.* Specifically, I invited the parties to address whether or not:

a. Merck acted in accordance with due care when it contracted with the Center for Disease Control ("CDC") to ensure the presence of a physician at inoculation or an adequate warning of the risks associated with vaccination was conveyed to recipients or to their parents or guardians, *id.* at 261;

b. the school nurse who supervised the MMR II inoculation was a learned intermediary, *id.* at 255;

c. the package circular contained an adequate warning of the revaccination risks, *id.* at 258;

d. the proximate cause element of a duty to warn claim had been satisfied,[2] *id.* at 262–63; and

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[2]As I pointed out above, at 698 n. 1, the proximate cause question will not be reached in this opinion.

e. the cause-in-fact element of a duty to warn claim had been satisfied,[3] *id.* at 266 and n. 33.

Merck's supplemental motion for summary judgement will be granted. Merck satisfied its duty to exercise reasonable care to inform the Mazurs of the vaccine's risks. Even though no doctor was present, Edith Frederick, the nurse who supervised the administration of the vaccine to Lisa Mazur, was a qualified learned intermediary. She was provided with a sufficient warning of the risks associated with MMR II inoculation. The package circular contained an adequate warning of vaccination risks and accurately reflected the medical evidence available in 1982. Therefore, Merck cannot be held liable for Lisa's illness.

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[3]Merck opted to reserve its challenge to the sufficiency of the Mazurs' proof of causation until a later date. *See supra* at 698 n. 1.

I. FACTS

The facts of this case are described in great detail in my prior opinion. *See Mazur*, 742 F.Supp. at 243–45. I will briefly summarize them here.

In response to a measles epidemic among school children in Philadelphia in the late 1970's, the City of Philadelphia, Department of Public Health ("health department") proposed a regulation, which was later adopted by the School Board of Health ("school board"), requiring all children attending a school in Philadelphia to be vaccinated against a variety of pediatric diseases. The school board's medical director, Dr. Robert G. Sharrar, selected Merck's MMR II vaccine for the simultaneous immunization against measles, mumps, and rubella. Affidavit of Robert G. Sharrar, M.D. ("Sharrar aff."), ¶ 8, attached as Merck's exhibit J.

MMR II was packaged in containers which included an insert describing the risks and benefits associated with

its use.[4] The school board purchased the MMR II vaccines from the CDC which had, in turn, purchased then from Merck. The Merck–CDC purchase contract stated the CDC would assure that a physician be present at each inoculation or that the CDC would provide MMR II recipients or their

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[4]The April, 1981, package insert or circular contained the following pertinent information about the risk of contracting SSPE from the MMR II vaccine:

> There have reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccination distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5–10 cases of SSPE per million cases of measles. The results of a retrospective case–controlled study conducted by the Centers for Disease Control suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent risk of SSPE.

parents with what Merck and it believed to be an adequate warning of the risks associated with MMR II immunization. Opting to proceed under the latter clause, the CDC drafted an "Important Information Statement" to be sent to all parents of school-age children. Affidavit of William B. Freilich, ("Freilich aff."), ¶ 22 and exhibit 6, attached as Merck's exhibit E. The Important Information Statement was sent to parents via their children.

Lisa Mazur received the MMR II vaccine on February 26, 1982. The vaccine was administered at Lisa's school under the supervision of Edith B. Frederick, a registered nurse. Mrs. Mazur claims she never gave her consent for her daughter's vaccination. She denies receiving an Important Information Statement or any other warning about MMR II's risks. She did, however, become aware of the scheduled immunization, protested Lisa's vaccination to the school board, and so she would not be vaccinated kept

Lisa out of school for a week prior to the date of the vaccination.

On November 2, 1983, Lisa was diagnosed as having SSPE.[5]

II. DUTY TO WARN

A. The Manufacturer's Duty to Warn.

In my prior opinion in this case, I described and explained the nature and scope of a vaccine manufacturer's duty to warn. *See Mazur*, 742 F.Supp. at 251–53. I need

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[5]SSPE is a slowly progressing, inflammatory disease of the central nervous system. SSPE most often attacks children under twenty years of age. Its onset is marked by mental deterioration and psychological disturbances. Neurological and motor dysfunctions, such as convulsions, seizures, visual difficulties, and myoclonic jerks, are often present. Death usually occurs within one to three years. *See, e.g., The Merck Manual*, 2041 (Merck Sharp & Dohme Research Laboratories, 15th ed. 1987); *Harrison's Principals of Internal Medicine*, 2096 (R. Petersdorf, 10th ed. 1983). Lisa is still alive, but is presently incapacitated.

not go into such a thorough review here, but a few comments are necessary.

[1] The standard of care which applies in this case is set forth in Restatement (Second) of Torts § 388.[6] "Under this section, the supplier has a *duty to exercise reasonable care* to inform those for whose use the article is supplied of the facts which make it likely to be dangerous."

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[6]Section 388 provides in pertinent part:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier
> (a) Knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and
> (b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and
> (c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

Incollingo v. Ewing, 444 Pa. 263, 282 A.2d 206, 219 n. 9 (1971) (emphasis added). Because MMR II is a prescription drug product, Merck can satisfy its duty to warn the vaccine recipient by exercising reasonable care to provide an adequate warning to a medical professional who acts as a "learned intermediary." *Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974). The "learned intermediary rule" recognizes that a medical professional is qualified by knowledge, experience, and preparation to exercise his "individual medical judgment bottomed on a knowledge of both patient and palliative." *Id.*

[2] If the vaccine is "dispensed to all comers at mass immunization clinics without an indivualized balancing by a physician of the risks involved..., [i]t is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by

obligating the purchaser to give warning." *Davis v. Wyeth Laboratories*, 399 F.2d 121, 131 (9th Cir.1968). Although this principle has been called the "mass immunization exception" the learned intermediary rule,[7] *see, e.g., Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1178–79 (5th Cir.1989), it is really one of several circumstances when the duty to warn the user directly is imposed on the manufacturer.

If the manufacturer chooses to obligate the purchaser of the vaccine to give warning, permissible under *Davis* and comment n of section 388, the general rule controls and the manufacturer's warning activities must be examined to see if they comport with its "duty to exercise reasonable care to

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[7]I found previously that mass immunization principles did not apply in this case because the health department program was not a "mass immunization," the vaccine was not dispensed to "all comers," individualized medical judgments were made that excluded two–thirds of the potential recipient pool, and Merck could not have foreseen that no learned intermediary would be present at inoculations. *Mazur*, 742 F.Supp. at 255–57.

inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Incollingo,* 282 A.2d at 219 n. 9. The issue of whether or not the reasonableness standard has been met will most likely turn on the issue of foreseeability, (*i.e.*, "was it foreseeable that the purchaser would not provide an adequate warning to the consumer?" or "was it foreseeable that a learned intermediary would not be present at inoculation?"). If the manufacturer acts in accordance with due care it cannot be liable for the injuries that happen to befall the plaintiff.

B. The Parties' Contentions.

The Mazurs charge Merck with failing to warn them of MMR II's risks before Lisa was inoculated. They allege that they never received any warning from Merck, the CDC, the health department, or the school board. The Mazurs posit claims for strict liability and negligence for failure to warn. These claims depend on proof of four facts: (1)

Merck had a duty to warn adequately Lisa or her parents or a learned intermediary of the health hazards associated with MMR II use; (2) Merck breached that duty; (3) Merck's breach in fact caused Lisa's illness;[8] and (4) Merck's breach proximately caused her illness.[9]

Merck argues it had no duty to warn the Mazurs directly and it fulfilled its duty to warn by entering into and relying on its purchase contract with the CDC. It contends its transactions with the CDC were in accordance with its "duty to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous." *Incollingo*, 282 A.2d at 219 n. 9. Merck also asserts it did not have a duty to warn Lisa or her parents directly, because Nurse Frederick was qualified and in fact acted as a "learned intermediary," *Reyes*, 498 F.2d

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[8]*See supra* at 698 n. 1.

[9]*See supra* at 698 n. 1.

at 1276, at the time Lisa received the MMR II inoculation. Thus, Merck argues it need only have made an adequate package circular available to Nurse Frederick. It posits that it has done so. Additionally, it also maintains that the Mazurs' contention that the revaccination warning was inadequate is without merit.

With that background in mind, I will first discuss whether Merck acted in accordance with due care when it contracted with and relied upon the CDC to provide a physician or the Important Information Statement to parents. It did. I will then consider whether or not Nurse Frederick was a learned intermediary. She was. Because she was, I will next address whether a warning was made available to her. It was. Finally, I will analyze whether the package circular contained an adequate warning of the revaccination risks. It did. Thus, Merck is entitled to summary judgment in its favor.

III. DISCUSSION

A. Merck Discharged Its Duty To Warn Through The CDC Contract.

[3] Merck is not responsible for Lisa's injuries if it acted reasonably when it contracted with the CDC and relied upon its guarantee that the MMR II vaccine would be administered by a physician or after a meaningful warning had been provided to Lisa or her parents. *Mazur*, 742 F.Supp. at 260–61.

In the mid–1970's, following *Davis v. Wyeth Laboratories, Inc.*, 399 F.2d 121 (9th Cir.1968) and *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974), Merck reconsidered its vaccine distribution policies. Freilich dep. at 109. With these mass immunization decisions, the courts had created the possibility for expanded liability, but they had given Merck an out by permitting it to assign warning tasks to an intermediate

purchaser. *Davis*, 399 F.2d at 130; *Reyes*, 498 F.2d at 1276–77. William Freilich, Merck's in–house counsel at the time, focused on the latter. He saw a way for "Merck to limit its liability exposure based on the *Reyes* case." Freilich dep. at 109. He proposed Merck, other vaccine manufacturers, CDC representatives, the Immunization Practices Advisory Committee ("ACIP"), the Bureau of Biologics, the Food and Drug Administration, the Committee on Infectious Diseases of the American Academy of Pediatrics ("Redbook Committee"), state public health departments, and representatives of parent and consumer groups meet to discuss alternatives programs. *Id.* at 23. At the meeting, three alternatives were suggested. *Id.* at 109–10.

The first proposal was to require manufacturers to be responsible for vaccine administration throughout the country. *Id.* at 23 and 107. According to Freilich, this "ridiculous" idea was dismissed rather readily because none

of the manufacturers had any experience in public health administration issues and there were a wide variety and large number of public health agencies and experts in a better position to deal with large-scale immunization. *Id.* at 24 and 107-08.

The second suggestion, one that was adopted by all of the participants at the meeting, was to lobby for the establishment of a no-fault compensation fund for children injured as a result of immunizations. The National Childhood Vaccines Injury Act of 1986, 42 U.S.C. §§ 300aa-33, was the product of this legislative initiative. *See Mazur*, 742 F.Supp. at 246-47.

The third alternative, one that was adopted by Merck and the CDC, was to require the CDC, as the primary purchaser of Merck's MMR II vaccines, to disseminate warnings to individuals who would receive the vaccine as part of a public health program. Freilich dep. at 143 Freilich talked to each of the participants at the meetings

before he made his determination that the Merck-CDC purchase contract was the best means to ensure that a warning was provided to vaccine recipients in order to limit Merck's liability exposure. *Id.* at 143-49.

To that end, in the late 1970's and early 1980's, Merck and the CDC entered into three contracts for the sale and purchase of MMR II. The Merck-CDC purchase contract provided in pertinent part that the CDC:

> represents and agrees that it will (1) take all appropriate steps to assure that all vaccine supplied to various locations within the 50 states,... pursuant to the terms of this contract, shall be administered to each patient on the basis of an individualized medical judgment by a physician, or (2) take all appropriate steps to provide to such a patient (or to the patient's parent or guardian) meaningful warnings relating the risks and benefits of vaccination, in form and language understandable to such patient, parent or guardian.

Freilich aff. at ¶ 17 and exhibits 3, 4, and 5 attached thereto. Freilich drafted most of the "duty to warn clause," Freilich dep. at 177, but both Merck and the CDC

negotiated the contract, *id.* at 178–79, and the CDC made proposals which were eventually included in the final document, *id.* at 183–84.

Soon after entering into the contracts, the CDC set out to draft a comprehensible, yet substantively adequate warning for vaccine recipients or their parents.[10] The Important Information Statement was intended to serve that purpose. The CDC drafted an Important Information Statement for all the vaccines it provided to local public

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[10]The CDC never proceeded on a plan to ensure the presence of a physician at each inoculation. It selected the alternative route and required local health agencies to use the Important Information Statement. If, like here, the local health agency required a learned intermediary to be present at inoculation, the vaccine manufacturer cannot be held liable even if the local health agency or the CDC failed to disseminate the Important Information Statement. In other words, even though the Merck–CDC contract called for the CDC to ensure that a physician would be present at each inoculation–and even though that was not done so far as Lisa Mazur was concerned–the presence of a learned intermediary, Nurse Edith Frederick, *see infra* at 708–711, precludes imposing responsibility for Lisa's ensuing illness on Merck.

health agencies. For its sources for the measles, mumps, and rubella Important Information Statement, the CDC used Merck's MMR II package circular, previous CDC studies, and its own general expertise in the fields of vaccine safety and administration. Freilich aff. ¶¶ 24–25. Merck did not materially participate in the preparation of the Important Information Statement, except for providing the CDC with the package circulars. Freilich aff. at ¶ 25.

The CDC obligated, as a condition of purchase, the state and local health agencies, such as the health department, to provide vaccine recipients or their parents with the appropriate Important Information Statements. Freilich aff. 2 at ¶ 22; Childhood Immunization Project Grants: Guidelines for Applications, February, 1980, at 10.[11] The health department distributed the Important

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[11]The Guidelines provide:

VI. USE OF INFORMATION STATEMENTS ON RISKS AND BENEFITS OF VACCINATION

Information Statements during the 1981-82 immunization program.[12] Deposition of Herbert Hazan, at 25-26, attached as Merck's exhibit F.

The Mazur's charge it was not reasonable for Merck to rely on the CDC because: (1) Merck was improperly

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A. In order to assure appropriate provision of information relating to risks and benefits of vaccination in programs for which funds are made available pursuant to this grant, grantees shall take the following steps:

1. Establish procedures for providing copies of the appropriate "Important Information" forms ... to all vaccinees (parents or guardians) receiving vaccinations in public clinic settings.... Any other addition to the forms, or variation from the language or format of them, must have prior written approval of the [CDC].

[12]In the first round of motions, the Mazurs argued the fact that Mrs. Mazur never received an Important Information Statement from the health department showed that Merck acted unreasonably in relying on the CDC to provide a warning to her. *Mazur*, 742 F.Supp. at 261. I rejected this argument because the relevant issue is not whether she actually got an Important Information Statement, but whether Merck could foresee she would not get one. *Id.*

motivated to do so; (2) Merck knew the difficulty in drafting an adequate warning directed to the recipient or her parents; (3) Merck knew the CDC would draft an Important Information Statement which downplayed the real risks of MMR II inoculation in order to increase the number of recipients; (4) Merck knew earlier versions of the Important Information Statement were sometimes not read or not understood by the recipient or her parents; and (5) Merck failed to investigate initially and to monitor continually the CDC's performance under the contract. Merck contends it contracted with the CDC, after careful negotiation and planning, because the CDC was in the best position to provide vaccine recipients with a meaningful warning and it had no reason to doubt that the CDC would not do so. I conclude Merck acted in accordance with its duty of care and the Mazur's arguments to the contrary must be rejected.

1. *Merck's Motivation Is Irrelevant.*

The Mazurs charge Merck with unreasonable conduct because of its attempt "to limit its liability exposure." Freilich dep. at 109. The Mazurs assert "that the impetus for these meetings was not to devise the best method for warning the public of vaccine risks, but to devise a way for Merck and other vaccine manufacturers to continue to market vaccines, while at the same time insulating themselves from the specter of liability raised by the *Reyes* case." Mazur's resp. at 18. I will assume this is so, despite the absence of proof that it is. There is no requirement, however, that Merck be an altruist before it can avoid liability. If that were the case, Merck should be blamed for charging the CDC for the vaccines–it should have provided them free. Merck is permitted, under the very decision the Mazurs assert prompted this allegedly unscrupulous behavior, to obligate a third party to carry out its warning tasks. *Reyes*, 498 F.2d at 1276. That Merck

may have done so to limit its liability exposure rather than for altruistic or humanitarian reasons is of no consequence.

If the Mazurs' argument is taken to the extreme, few suppliers could ever escape liability for the injuries which their products cause, because most suppliers act with a profit motive rather than with an altruistic one. Limiting liability exposure is one way of maintaining whatever profit sales create. I am certainly not prepared to foist liability onto every manufacturer, distributor, or retailer because it acts in its own self-interest; any warning, whether provided by Merck or the CDC, was intended to limit Merck's liability. Merck could supply its vaccine products without a warning, and face devastating consequences in the form of law suits and criminal sanctions. A warning limits the chance such things might happen. Merck's motivation in relying on the CDC is not relevant to the issue of whether Merck acted in accordance with due care.

2. *Merck Reasonably Relied On The CDC To Draft The Important Information Statement.*

The Mazurs' second argument focuses on Merck's unsuccessful attempt to draft a package circular which could be understood by patients. They argue since Merck knew it was very difficult to create such a warning, it should have known the CDC would not be up to the task. Essentially, they charge if Merck knew creating an understandable warning was hard, it acted unreasonably when it required the CDC to come up with one.

This argument relies on a mischaracterization of Freilich's deposition testimony. Freilich freely admitted Merck had tried and failed to develop a "*package circular*" that would be comprehensible to vaccine recipients or their parents. Freilich dep. at 120, 123–25, 127–33, 135–36, and 140–41. Freilich also stated, however, a "*consent form*" or an "*important information form*" can be written for lay understanding. *Id.* at 135. The Mazurs glide over the

highlighted terms and attempt to equate them. Freilich explained that a "patient package circular," *id.* at 140, was different than an important information form in that a patient package circular must contain "all recommendations and knowledge that a manufacturer feels is relevant and important to accompany its product, and ... required ... by the Federal Government.... And that package circular is required to accompany the product when it's sold in interstate commerce." *Id.* at 136. Clearly, what Freilich was talking about was a document that complied with all the requirements of federal drug regulations and was still comprehensible to a lay person. Merck found the terms required under federal law to be too technical to be explained in ordinary language. *Id.* at 140–41. Merck was also concerned about the possibility the patient package circular would not reach the patient because it would be placed in the vaccine container which is often not made available to the patient. *Id.* at 142. In light of these facts

and given Merck's belief that a comprehensible warning, not necessarily a patient package circular, could be drafted, it was reasonable to assign the task of creating and disseminating a separate document, the Important Information Statement, to the CDC.

3. *The CDC Did Not Downplay The Risk.*

The Mazurs' next contention is the most specious. Basically, they charge Merck should not have trusted the CDC, because Merck knew or should have known the CDC willfully downplays the risks inherent in MMR II vaccination in order to entice children into receiving the vaccine. This contention must be rejected for a number of reasons.

First, the Important Information Statement does not downplay the risks associated with MMR II inoculation. The October 1, 1980, Important Information Statement, the

one used in the 1981–82 immunization drive, carefully and clearly describes the grave dangers which could result from measles, mumps, and rubella. Then, it explains who should receive the correlating vaccines. The side effects of the vaccines are stated:

> About 1 out of every 5 children will get a rash or slight fever 1 or 2 weeks after getting measles vaccine lasting for a few days. Occasionally there is mild swelling of the salivary glands after mumps vaccination. Although experts are not sure, it seems that very rarely children who get these vaccines may have a more serious reaction, such as inflammation of the brain (encephalitis), convulsions with fever, or nerve deafness.
>
> About 1 out of every 7 children who get rubella vaccine will get a rash or some swelling of the glands of the neck 1 or 2 weeks after the shot. About 1 out of every 20 children who get rubella vaccine will have some aching or swelling of the joints. This may happen anywhere from 2 to 10 weeks after the shot. It usually lasts 2 or 3 days. Adults are more likely to have these problems with their joints–as many as 1 in 4 may have them. Other side effects, such as pain, numbness, or tingling in the hands and feet have also occurred but are very uncommon.

> With any vaccine or drug, there is a possibility that allergic or more serious reactions or even death could occur.

A warning which plainly states that encephalitis, convulsions with fever, nerve deafness, serious reactions, or death may follow immunization is not what a reasonable juror would call "downplaying" a vaccine's risks. Those warnings were accurate given the state of medical knowledge in 1982, *see infra* at 40–45, and were in a form and in terms the intended reader would understand. Had a vaccine recipient and his parents read the Important Information Statement, they would have understood the real risks associated with MMR II inoculation.

The Mazurs, through their expert Dr. Kevin C. Geraghty, contend that there were five inadequacies, *i.e.*, areas in which the CDC downplayed the true risks, in the

1980 Important Information Statement which made Merck's reliance on the CDC unreasonable[13].

1. the terms encephalitis is not properly described;

2. a proper revaccination warning is not included;

3. certain possible side effects of the measles vaccine, such as permanent brain damage, blindness, and/or death, are not listed;

4. recipients should have been warned to defer vaccination until after consultation with a physician if they had been hospitalized within the previous 90 days; and

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[13]The Mazurs cogently argue that the language of the Important Information Statement is relevant to whether Merck exercised reasonable care to inform them of the risks of MMR II inoculation, because, for example, if Merck had authorized the CDC to disseminate the Important Information Statement in Latin, as opposed to English, with the knowledge that very few people understand Latin, that would not be in accordance with due care. Similarly, it would not be reasonable for a manufacturer to ask a delivery company if its trucks were safe when it knew that the drivers of the trucks were blind, and then nonetheless award a delivery contract to the delivery company. Therefore, I will examine the Important Information Statement to determine if Merck acted reasonably when it relied upon the CDC to issue it.

5. recipients should have been warned to defer vaccination until after consultation with a physician if they had recently received prescription medication.

Affidavit of Kevin C. Geraghty, ("Geraghty aff.") at ¶ 35, attached as Mazurs' exhibit 57. These alleged deficiencies in the Important Information Statement are without merit. Except for the revaccination complaint, which I will discuss and reject in the package circular portion of this opinion, *infra* at 40–45, I will consider these allegations in turn.

First, the encephalitis charge: it is important to note that the term encephalitis is used to further specify the lay description "inflammation of the brain." Thus, Dr. Geraghty's accusation is calculated to mislead since the term encephalitis is in and of itself a description of a condition. More significant is the fact that encephalitis is defined in *Dorland's Illustrated Medical Dictionary*, 483 (24th ed. 1965) as "inflammation of the brain." Dr. Geraghty's complaint is disingenuous. It is difficult to understand how the term encephalitis could be better

described to a layman than by its definition. Certainly, there are types of encephalitis, SSPE, for example, which could have been listed but that would not have aided the lay reader because she would not understand what the terms meant. "Inflammation of the brain" adequately describes and defines encephalitis for the intended reader of the Important Information Statement.

I agree that the Important Information Statement does not use the words "brain damage" or "blindness," but the clear impression it leaves is that these medical problems could result from the inoculation. "Inflammation of the brain" describes damage to the brain, death is listed as a possible consequence of immunization, and although blindness is not among the warnings, it is encompassed in the unspecified "serious reaction" category. Even if blindness could not be so included, Dr. Geraghty does not identify any medical research that would support the

inclusion of the term in the Important Information Statement.[14]

The ninety-day and prescription drug limitations are similarly unsupported by the medical evidence available in February, 1982. Dr. Geraghty does not refer me to a single article predating 1982 that concludes the physical health of the vaccine recipient is a causative factor in the onset of illness following measles, mumps, and rubella vaccination. Dr. Geraghty also does not explain what the problem is with the Statement's warning that:

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[14]Dr. Geraghty relies, in part, I assume, on Kazarian, *Optic Neuritis Complicating Measles, Mumps, and Rubella Vaccination*, 86 American Journal of Ophthalmology 544 (1978), to support his opinion. That article, however, merely concludes there is a possible relationship between the trivalent measles, mumps, and rubella vaccine and optic neuritis. The patient which the article describes was temporarily without sight in his left eye and that eye was to some degree impaired for over a year. Optic neuritis is an inflammation of the optic nerve. A possible correlation between the vaccine and optic neuritis would not create the necessity of a special warning for possible blindness in light of the other serious side effects described within the Important Information Statement.

SOME PERSONS SHOULD NOT TAKE THESE VACCINES WITHOUT CHECKING WITH A DOCTOR:

* Those who are sick right now with something more serious than a cold

* Those with an allergy to an antibiotic called neomycin.

* Those with cancer or leukemia or lymphoma.

* Those with diseases that lower the body's resistance to diseases.

* Those with diseases that lower the body's resistance to infection such as cortisone or prednisone.

* Those who have received gamma globulin within the preceding 3 months.

(emphasis in original). These warnings adequately apprise the vaccine recipient or his parents that the physical health of the recipient at the time of and immediately before the inoculation is an important factor in the immunization determination, one that should be analyzed by a medical professional. In sum, there is nothing about the wording of

the Important Information Statement which made its use by the CDC and Merck unreasonable.

Second, were I to accept the argument that Merck knew or should have known the CDC would mislead children and their parents about the risks inherent in MMR II inoculation to increase the number of vaccinations, I would have to find the very agency created to promote and to protect the public welfare cannot be trusted. The Mazurs provided me with no reason to do so. The CDC is an agency of the Public Health Service of the United States Department of Health and Human Services. It is empowered to conduct studies, evaluations, tests, and emergency programs in order to prevent the spread of disease and to improve public welfare. With respect to vaccines, it plays a vital role in research, development, testing, and distribution. 42 U.S.C. § 300aa–2; Freilich aff. at ¶ 9. It publishes the *Morbidity and Mortality Weekly Report*, among other reports, studies, and journals, to

educate public health and medical professionals about the risks and benefits of immunization. Freilich aff. at ¶ 11. One of its more important functions is to provide financial and medical assistance to state and local health agencies, such as the health department, so they can operate immunization programs. It performs that function to increase the number of vaccine recipients, because that makes for a healthier populace. There is nothing improper with this goal and there is no evidence from which I can conclude the CDC sought to achieve this goal by lulling potential recipients into a false sense of security about the risks of immunization. The Mazurs have not offered a shred of proof the CDC ever intentionally falsified a warning, left out a key warning, encouraged certain individuals to receive the vaccines without the benefit of a physician's counsel, artificially inflated the efficacy and safety of immunization, or did anything that would create

an unnecessary risk of harm to potential vaccine recipients.[15] Merck could rely on the CDC to carry out its public health functions without fear the CDC would downplay MMR II's hazards to place individuals like Lisa Mazur in a position to receive it when they should not.

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[15]"Unnecessary risk" is the risk above and beyond that which is inherent in the vaccine, *i.e.*, a risk that results from the distribution of the vaccine to someone who should not receive it rather than from the distribution of the vaccine to someone who should receive it. As I noted in my first opinion, the MMR II vaccine falls within the category of "unavoidably unsafe products," *Incollingo v. Ewing*, 444 Pa. 263, 287, 282 A.2d 206, 219 (1971) (quoting, Restatement (Second) of Torts, § 402A, comment k). *Mazur*, 742 F.Supp. at 251.

4. *The Statement-Comprehension Study Imposed No Duty On Merck.*

In 1977, the CDC conducted a study of lay comprehension of the various Important Information Statements it used to warn vaccine recipients. Mazurs' exhibit 47, a memorandum from Alan R. Hinman, M.D., Director, Immunization Division of the CDC ("Hinman memo."). Test subjects were provided with the Important Information Statements for five childhood vaccines: DTP, polio, measles, mumps, and rubella. The results of the study were not particularly encouraging, because those who read the Important Information Statement did not always understand it.[16] Hinman memo. The Mazurs argue Merck

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[16]Dr. Hinman reported these general impressions:

> a. 19.7-29% did not read the entire form;
> b. 8.2-13.8% did *not* feel they understood what they read; 0.7-3.0% did *not* feel they understood what they were told;
> c. Only 2 people refused immunization after reading the forms (1 polio, 1 DTP); and

knew of the study, although it appears it was not necessarily aware of the results, *see* Freilich dep. at 150, and should have known informed consent was "exceedingly difficult" to obtain. Therefore, they contend Merck should not have relied on the CDC to convey an adequate warning. Even if I were to assume Merck knew the results of the 1977 study, it does not follow Merck knew or should have known the October, 1980, measles, mumps, and rubella vaccine Important Information Statement would not be understood.

At the time of the 1977 study, the measles, mumps, and rubella vaccine Important Information Statements were separate forms. Hinman memo. In his memorandum, Dr. Hinman clearly states later versions of the statements would be revised and would appear on one form. *Id.* Thus, the

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d. For each question asked about the disease, the vaccine, number of doses, precautions, etc., a fairly steady 12-25% responded "don't know." Hinman memo. (emphasis in original).

1980 Important Information Statement was a different and, apparently, improved warning. Dr. Hinman stated in his deposition that "we do not have a specific indicator based on subsequent [to 1977] similar field trials of the degree of comprehension of the forms." Hinman dep. at 101, attached as Mazurs' exhibit 46. Dr. Hinman admits, then, there has been no comprehension study of the 1980 MMR II form. The Mazurs have not shown otherwise.

Moreover, Dr. Hinman also admitted the "results of the ... [1977] study were not very understandable ... and the report of the pilot study itself is incomprehensible." *Id.* This calls into question whether the 1977 study is even a valid report in the eyes of the agency that conducted it. I am not persuaded Merck should be bound by a study the CDC considers "incomprehensible."

5. Merck's Investigation of the CDC Was Sufficient

Finally, the Mazurs complain Merck did not properly investigate the CDC's capability to disseminate an adequate warning and failed to monitor the CDC's performance under the contract. The Mazurs assert this lack of diligence rendered Merck's decision to rely on the CDC unreasonable. There are two problems with this contention. First, the Mazurs have not introduced a single bit of proof, other than Mrs. Mazur's own self-serving declaration, that the CDC was not disseminating Important Information Statements. The Mazurs have had ample opportunity to create some doubt as to the CDC's performance under the contract. They have not done so.

Second, Merck did investigate, before and after the contract was signed, the CDC's performance and found it to be more than satisfactory. Merck initially selected the CDC as the vehicle through which it would provide adequate

warnings to consumers because the CDC sold the vaccine to the state and local health organizations, supervised the distribution of vaccines, and had vastly more experience than Merck did in the public health field. Merck based its decision on its own past experience with the CDC; recommendations from physicians, the Bureau of Biologics, consumer groups; and on conversations with the CDC. Freilich dep. at 144. After it made its decision, it monitored the CDC's performance through conversations with these same individuals and others. Freilich states he and other employees at Merck spoke with the CDC, private physicians affiliated with the American Academy of Pediatrics, the Bureau of Biologics, parent and consumer groups, and members of the Redbook Committee. *Id.* at 145–46, 195, and 306. Each one of these sources told him and the other employees that consent forms and Important Information Statements were being sent out by the CDC and, in turn, to parents by local health organizations

participating in CDC immunization programs. *Id.* at 145–47, 154, 195–96, 306–09. In fact, one parent group representative complained that the use of the consent forms was "barring their recovery in lawsuits." *Id.* at 154. Through its regular contact with these sources Merck continually checked the CDC's dissemination efforts. At no time did it appear the CDC was not doing its job. Merck might have been more thorough in its examination; for example, it could have hired an independent contractor to review the CDC's conduct, but the results would have been the same. The CDC was disseminating an adequate warning to vaccine recipients. In the end, Merck, whether the source of its information was its own employees or an independent contractor, could not have foreseen that Mrs. Mazur would not receive an Important Information Statement which contained an adequate warning of the risks of MMR II immunization. Accordingly, Merck exercised

reasonable care to be sure the Mazurs were informed directly of the risks of MMR II vaccinations.

B. *Nurse Frederick Was A Learned Intermediary*

[4] Merck's contract with the CDC provided the CDC was to take appropriate steps to ensure the presence of a physician at each inoculation or give warning to the potential vaccine recipient of the risks involved. The CDC did not impose the physician requirement in the Philadelphia inoculation program. Nevertheless, the health department had a school nurse present at inoculation.

In my first opinion, I predicted the Pennsylvania courts would hold that, in appropriate circumstances, a nurse can act as a learned intermediary. *See Mazur,* 742 F.Supp. at 253–55. I need not revisit that issue here and will only review the record to determine if in fact Nurse Frederick was a learned intermediary on February 25, 1982.

That determination will depend on her qualifications as a medical professional, her knowledge of and experience with vaccine administration to school children, nd whether she made considered medical judgments with regard to the children entrusted to her care.

Edith Frederick has been a registered nurse in Pennsylvania since 1949. Shortly after receiving her nursing certificate she gained practical experience in several hospitals and psychiatric clinics in this region. She had some exposure to pediatrics, but no special training or experience with vaccine administration. As a registered nurse, she cannot prescribe drugs but can administer or dispense previously prescribed drugs. Frederick dep. II at 53.

Nurse Frederick received her bachelor of science degree in education from Temple University in 1971 or 1972 and her master's equivalency degree in education from the same school in 1976. She has not written a master's

thesis. She received additional training in a nurse practitioner program at the Hospital of the University of Pennsylvania ("HUP") during the 1980–81 school year. *Id.* at 9. Classes met once a week on Saturdays and lasted the entire day. Nurse Frederick volunteered for the program, which was funded by the school board. *Id.* at 10. The HUP program was intended to provide a review of the basic health courses such as anatomy and physiology. It had a special focus on physical examinations of children. *Id.* at 58–59. The program did not include vaccine training or education. *Id.* at 59.

Nurse Frederick began her employment with the school board as a school nurse in 1964. Her first assignment was at Olney High School where she trained under two more experienced nurses. She received no immunization experience at that school. She was transferred to two other schools for the next year, but once again was not involved in an immunization program.

In 1968, Nurse Frederick was placed at the Morrison School, which Lisa Mazur would later attend. Nurse Frederick worked there three days each week and at another school two days. The Morrison School had approximately six hundred students. Nurse Frederick described herself as the "contact person" Morrison school parents would call if they had questions about their child's health or a vaccine program. *Id.* at 23.

At the time Lisa received her vaccination in February, 1982, Nurse Frederick had seen other students with measles and had seen and could thoroughly describe the symptoms of the disease. *Id.* at 23–24. She knew the complications that could arise from measles, such as hearing problems, meningitis, and encephalitis. *Id.* at 24. She also knew that side effects of a measles vaccine were possible hearing loss, meningitis, encephalitis, and death. *Id.* at 25 and 88–89. She did not know SSPE was a possible complication of a measles infection or the measles

vaccine. *Id.* at 88. She was not aware if the mumps vaccine produced any side effects, although she knew the mumps virus can cause testicular problems. *Id.* 88–89. As for rubella, she was aware both the virus and the vaccine may be harmful to pregnant students and their babies. *Id.* at 89–90. While Nurse Frederick knew and understood the complications and side effects of both the diseases and the vaccines to prevent the diseases, she could not state how a virus travels through the body, how a virus causes illness, or how a vaccine prevents illness. *id.* at 88–89.

She got her information on the three diseases and the related vaccines from her general experience in the school health field, materials issued by the school board, medical journals to which she subscribes and reads, unknown articles, periodic health bulletins distributed by the school board and the health department, and the Important Information Statements provided to her for distribution to students. *Id.* at 27–28 and 90–93. In the years prior to the

1981–82 immunization drive, Nurse Frederick also participated in two or three other, smaller immunization programs at the Morrison School. Those programs were optional, whereas the 1981–82 drive was mandatory for all students. The administration of the vaccines operated essentially in the same way as the larger drive in 1982. *See infra* at 710.

In 1981, all school nurses were required to attend a district meeting to discuss the immunization program and to receive instructions as to how each nurse should administer it. Frederick dep. II at 31. The district administrators and nurse supervisors instructed the nurses on how to select children based on their school health records, to inform children of the program, to amass packets of information for parents, to send that information to parents, to screen children at vaccination, and to update records after vaccination. The nurses received a copy of the Important Information Statement, which was used to

discuss the risks and benefits of vaccination during the meeting, *id.* at 95 and 97; a permission letter from Dr. Herbert Hazan, a school board health director, for parents to read and return to the school, *id.* at 95; and a list of instructions as to how to go about setting up the immunization program in each school. *Id.* The supervisors reviewed and explained each of the documents for the nurses. *Id.* at 31 and 97.

When Nurse Frederick returned to the Morrison School she began the record review to determine which, if any, vaccine each student needed. She spent four hours a day for approximately two weeks poring over the medical records. *Id.* She called certain parents whose children had a special health problem to inform them of the immunization program. *Id.* at 33–35. Nurse Frederick prepared the documents to be sent to parents and reviewed them before she passed them out. *Id.* at 102 and 105. She re-read the Important Information Statement at that time.

Id. at 102. She provided each homeroom teacher with a packet of information for each student with that student's name on it. The packet included the letter and permission slip from Dr. Hazan and the Important Information Statement corresponding to the vaccine the student was scheduled to receive.

Before she handed out the packets to the students, she spent a few minutes with each class generally describing the program and the information they would receive and what they should do with it. *Id.* at 105–107. She warned middle and high school students if they were pregnant they should not receive any vaccines. *Id.* at 108.

When the permission slips were returned, Nurse Frederick checked them against her master list. In particular, she looked for additional health information from parents, such as special warnings or prior undocumented vaccinations. *Id.* at 115. She excluded children from her list based upon the information she received from their

parents. *Id.* She sent home to parents a flier indicating the date and time of the vaccination and arranged for certain parents to volunteer on that day. *Id.* at 129–30.

On February 26, 1982, the date of inoculation, she returned the consent forms to the students so they could hand them back to her when they reached the head of the line. She and the technician who administered the vaccines placed themselves in the center of the Morrison School gymnasium. She brought the school medical records, a list of children with special medical problems, and some basic medical equipment: band aids, cotton balls, and thermometers. *Id.* at 132. As the students reached her, she took their consent form, checked it against her medical records and special listing, determined which vaccine was appropriate, and told the technician which one to give the students. *Id.* at 133. She also cursorily examined the children as they went past her. She assessed how each child appeared and behaved. *Id.* at 141. Specifically, she

was looking for signs of lethargy, runny eyes and noses, coughing, or sneezing. *Id.* Sometimes she asked students how they were feeling. *Id.* Children on her special listing of health problems received a more thorough examination. *Id.* at 147. Nurse Frederick stated she would have excluded students who did not appear healthy to her or told her that they were not feeling well. *Id.* at 38. Decisions to exclude students were within her decision and were final. *Id.*

Nurse Frederick did not ask any of the students about corticosteroid use, recent illnesses or operations, or about other medications being taken at that time. *Id.* at 146–48.

Nurse Frederick does not remember seeing the package circular before or during the inoculation. *Id.* at 98. It was not provided to her as part of the district meeting materials. *Id.* She was aware, however, the package circular came with each vial of the vaccine. *Id.*

At the conclusion of the program, Nurse Frederick went back into her school records to update them with the recent immunizations. *Id.* at 162.

Nurse Frederick vaguely remembers Lisa Mazur and can generally describe her. *Id.* at 175–76. She cannot remember Lisa's receiving a vaccine or anything about Lisa's condition.[17] *Id.* at 176.

Looking at the totality of her qualifications and what she did, it is clear that Nurse Frederick was acting as learned intermediary at the time of Lisa's inoculation. Nurse Frederick had the required general education, experience, and authority. She had specialized knowledge concerning the proposed treatment to be administered. she had read the Important Information Statement on at least

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[17]Nurse Frederick was not asked by counsel if she remembered if Lisa returned a consent form. Lisa's consent form is missing, but she did receive her shot. Additionally, Nurse Frederick was not asked if she would have let Lisa receive a vaccine if Lisa did not have a consent form.

two occasions before the vaccines were administered. She had particularized understanding of measles, mumps, and rubella; their symptoms and complications; and the vaccines intended to prevent them.[18] She knew some of the more common side effects of those vaccines. Specifically, she was aware than encephalitis could follow from the measles virus and the measles vaccine. It is important to note that

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[18]There is no question that Nurse Frederick's understanding of how the vaccines work in the body was less than complete. She could not state how the virus travels in the body, how the vaccine creates antibodies to ward off infection, or how it sometimes causes harmful side effects. This lack of understanding does not in and of itself disqualify her from being a learned intermediary. There is no requirement that the learned intermediary know everything there is to know about a particular drug product anymore than a complete understanding of the internal combustion engine is required before a person can be licensed to operate a motor vehicle. As long as she possessed enough knowledge of the "propensities of the drug," *Spychala v. g.D. Searle & Co.* 705 F.Supp. 1024, 1031 (D.N.J.1988), and of the patient to permit her to make an informed, individualized medical judgment, she was a learned intermediary. The requirement is not that she be the "*most* learned intermediary," just a "learned intermediary," which she clearly was on that day.

she did not prescribe MMR II, but she could and did direct when it was not to be given. She was an experienced medical professional with specific training as to the vaccine in question. In sum, her knowledge of the "palliative," *Reyes*, 498 F.2d at 1276, was sufficient. She was knowledgeable as to health issues of school-age children. Parents relied upon her expertise to aid them when they had questions concerning the school health programs and their child's needs. She reviewed the records of the children at the Morrison School and made individualized decisions concerning each of them.[19] On February 26, 1982, Nurse Frederick checked the students, including Lisa, for visible signs of illness. Ultimately, Nurse Frederick 'made a

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[19]Merck did not have to show that Nurse Frederick actually made an individualized medical judgment concerning Lisa's inoculation. It need only have shown that Nurse Frederick was a qualified learned intermediary, that is, *capable* of making an individualized medical judgment, and was present at the time of her inoculation. *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1179 (5th Cir.1988).

considered medical judgment," *Rohrbough v. Wyeth Laboratories, Inc.*, 719 F.Supp. 470, 478 (N.D.W. Va.1989), and permitted Lisa to receive her MMR II vaccine.[20]

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[20]In *Hurley v. Lederle Laboratories*, 863 F.2d 1173, 1179 (5th Cir. 1988), the court found the fact that a nurse administered the vaccine as a routine matter and the physician did not see the patient at the time of the vaccination because he was not in his office did not "bar the application of the learned intermediary doctrine to relieve the manufacturer of liability." The *Hurley* court based its decision on a finding that a physician–patient relationship existed and the doctor had assumed the role of learned intermediary. *Id.* The court reasoned that since the doctor assumed the burden of presiding over the patient's best interest, he, not the vaccine manufacturer, also assumed the corresponding duty to warn the patient. In other words, the vaccine manufacturer is not responsible for how the learned intermediary conducts his business. A recent decision in the Pennsylvania courts turned on that point. In *Taurino v. Ellen*, 397 Pa.Super. 50, 579 A.2d 925, 928 (1990), the court opined where a prescription drug manufacturer which had no reason to know that the learned intermediary would not administer the drug product but had provided an adequate warning to him, the manufacturer was not liable when the drug was dispensed to the plaintiff without an individualized medical judgment by the learned intermediary. The court stated that:

> [i]n such a case, the manufacturer fulfills its duty under the learned intermediary doctrine at the time it sells the product with adequate warnings directed to a physician. No new duty is created by the fact

C. *Merck's Warning to Learned Intermediaries.*

1. *Merck Provided A Warning: The Package Circular.*

[5] There is some dispute between the parties over whether a package circular, adequate or inadequate, was made available to Nurse Frederick. She cannot remember if she saw a package circular. Frederick dep. II at 98. She knows from prior experience, however, that in general a package circular is "the little folder that comes in with the bottle of vaccine." *Id.* The deposition testimony of Daniel S. Wood, Jr., the health department technician who administered the vaccines to the Morrison School children, is also somewhat unclear. Deposition Testimony

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> that after the sale no physician actually becomes involved in prescribing the drug. Although liability of a variety of kinds might then attach to the person providing the drug without the intervention of a physician, the manufacturer has no liability.... [T]o hold otherwise would be to confuse the duties of the manufacturer and of those other persons who later become involved in the provision of the drug. Taurino, *579 A.2d at 928.*

of Daniel S. Wood ("Wood dep."), at 51, attached as Merck's exhibit Q. It seems that Wood brought a few package circulars with him to the Morrison School, Wood dep. at 51, but he might not have made one available to Nurse Frederick. The parties differ as to whether Wood's actions suffice to make the circular available to her.

Both sides make more of this issue than is necessary. The resolution is quite simple. Merck exercised reasonable care to provide Nurse Frederick with a package circular because it enclosed one in every container of the MMR II vaccine sold to the CDC and the health department. Freilich aff. at ¶ 24. Wood confirmed that a package circular was in every package of MMR II vaccine he opened. Wood dep. at 50. The Mazurs do not contest Freilich's or Wood's statements. They have not suggested, let alone shown, Merck should have known the package circular would not reach Nurse Frederick (although one may have). Nurse Frederick knew where to locate a package

circular if she believed it necessary to perform her assumed tasks. If she had asked Wood for a package circular, he would have provided her with one. Wood dep. at 22 and 51. Even if he had thrown them all away before he arrived at the Morrison School, Merck cannot be held responsible for his actions. It satisfied its obligation when it provided the vaccines with package circulars to the CDC and the health department, which in turn made them available to Nurse Frederick. She could have seen a package circular had she wanted to do so. The possibility that she did not see one is not controlling of he issue of whether Merck exercised reasonable care to see that a warning would reach her. Merck took all reasonable steps to make sure a warning would be available to Nurse Frederick.

[6] It seems the Mazurs contend that unless there is affirmative proof the learned intermediary actually read the package circular, the vaccine manufacturer must be held liable. No case supports this contention; the law and

common sense are just the opposite. The vaccine manufacturer is not responsible for how the learned intermediary chooses to do her job. Once an adequate warning is made available, it is solely the responsibility of the learned intermediary to read it and inform the patient of its meaning as it may apply to him or her. *Hurley*, 863 F.2d at 1178–79; *Taurino*, 579 A.2d at 928. In *Walker v. Merck & Co., Inc.* 648 F.Supp. 931, 935–36 (M.D. Ga.1986), *aff'd without op.*, 831 F.2d 1069 (11th Cir.1987), the court found that once Merck provided an adequate warning of MMR II's risks to the plaintiff, it did not become an "insurer ..., and cannot be held liable for a consumer's failure to read or to listen to understandable warning." Similarly, here, Merck is not vicariously liable for Nurse Frederick's failings, if there were any. That Nurse Frederick may not have seen the package circular does not implicate Merck, which had previously exercised reasonable care to make an adequate warning available to

her. To suggest Merck had to have someone present at each inoculation of MMR II to double-check that the appropriate precautions were taken is ludicrous.

2. *The Warning Was Adequate.*[21]

[7] The April, 1981, MMR II package circular, the one in use during the 1981-1982 immunization program, included this revaccination warning:

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[21]The Mazurs argue in my prior opinion I foreclosed a second motion for summary judgment on the adequacy of the package circular. The Mazurs are incorrect. I found Merck did not address in the first round of briefing the revaccination claim asserted by the Mazurs, *Mazur*, 742 F.Supp. at 258, and I found the Mazurs raised a genuine issue of material fact concerning the adequacy of the MMR II revaccination warning, *id.* In my order I permitted the parties to conduct additional discovery and supplement their respective filings "on the duty to warn claims." *Id.* at 266. Clearly, the Mazurs' duty to warn claims included the charge the revaccination warning was inadequate. Merck properly moves for summary judgment on that charge at this time. In any event, the Mazurs responded to Merck's contentions, *see* Mazurs' surreply at 5-6, and had the opportunity to address more completely those contentions in its response and surreply.

> Revaccination: Based on available evidence, there is no reason to routinely revaccinate children originally vaccinated when 12 months of age or older; however, children vaccinated when younger than 12 months of age should be revaccinated. The decision to revaccinate should be based on evaluation of each individual case.

The Mazurs argue this statement was inadequate because it misstated the true revaccination risks. They propose the following language should have been included in the package circular:

> In the event you suspect your child received measles vaccine after the age of approximately 15 months, we strongly advise against repeating measles vaccine because of the small but *real* danger of brain damage.

Geraghty aff. ¶ 36.[22] Unfortunately for the Mazurs, they

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[22]Dr. Geraghty essentially contends that when the inherently dangerous MMR II vaccine is administered to previously-vaccinated individuals, especially those who seroconverted, *i.e.* developed immunity, after the first inoculation, the risk of serious illness multiplies. He suggests that a simple blood test should be given before a second dose of MMR II is prescribed to determine if the potential recipient has seroconverted initially; if so, he argues no second inoculation should be given to that person. The risk of illness, he maintains, is too high

did not introduce any evidence which shows Merck's warning was improper and they did not introduce any evidence which shows their proposed warning is proper. Merck, however, introduced substantial evidence that its warning was proper given the state of medical knowledge in 1982 and is certainly appropriate in light of the current medical evidence (and quite likely understates the importance of revaccination).

Dr. Geraghty proposed the change or addition to the package circular. Geraghty aff. at ¶ 36. He is fully qualified to propose a modification. *Mazur*, 742 F.Supp. at 263–64. His own affidavit, though, undercuts the weight to be given to his proposal and the medical evidence on which he relied does not support his proposal.

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relative to the minimal cost and effort of administering a blood test.

In his affidavit, ¶¶ 30–32, Dr. Geraghty described a number of inadequacies in the MMR II package circular.[23] He explains why each one is inadequate and how the inadequacy lead to Lisa's illness. Geraghty aff. at ¶¶ 30–31. Despite this rather exhaustive review of the package circular, he never opines that the revaccination warning was inadequate. In fact, there is no mention of the revaccination warning until the very end of his affidavit. *Id.* at ¶ 36. Even that statement shows his real concern is not what the package circular said about revaccination but what the Important Information Statement had not said about it. He claims that the package circular and the Important Information Statement should have included the warning described above. It can be seen from the language used by Dr. Geraghty that he intended parents, not learned intermediaries, read the warning. The "your child"

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[23]For a discussion of the merits of the alleged inadequacies see *Mazur*, 742 F.Supp. at 258–59.

reference could not and would not be included in a package circular. Dr. Geraghty may well have included this proposed modification to the package circular as an afterthought since it does not comport with his analysis of the package circular in his affidavit. Because of these internal inconsistencies, his opinion is entitled to little weight.

Dr. Geraghty's opinion is entitled to even less weight because it is not supported by the facts as they existed in 1982 and, without question, is not supported, indeed it is contradicted, by the facts in 1991. The adequacy of the MMR II package circular must be evaluated by what was known in the medical field at the time Lisa received her vaccine on February 26, 1982. *Liebowitz v. Ortho Pharmaceutical Corp.*, 224 Pa.Super. 418, 307 A.2d 449, 458 (1973).

Dr. Geraghty lists twenty-one scholarly articles he read to educate himself on the relationship between SSPE,

measles, and the measles vaccine. Geraghty aff. at ¶ 24. Only fifteen of them pre-date Lisa's vaccination. Not one of the fifteen articles shows an enhanced risk of brain damage following revaccination. In fact, only one of the articles even discusses the risks associated with measles revaccination and concludes that there is no proof of an enhanced risk of SSPE.[24] Dr. Geraghty must have been aware of the lack of support to be found in the twenty-one articles because his own summaries of them do not include any information about revaccination risks. *Id.* At best, the articles show a possible relationship, not necessarily

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[24]Halsey, *et al.*, *Risk Factors in Subacute Sclerosing Panencephalitis*: A *Case-Controlled Study*, 111 American Journal of Epidemiology 415 (1980). In the Halsey study, fifty-two children with SSPE were compared with ninety-eight healthy children controls. One of the aims of the study was to test "whether measles vaccine given to children who are immune to measles (from a measles infection or earlier vaccination) might contribute to the risk of developing SSPE." *Id.* at 422. The conclusion reached was: *"no evidence to support such a hypothesis was found in our study."* *Id.* (emphasis added).

causative, between the measles virus, wild or attenuated, and SSPE. From this, I gather, Dr. Geraghty's extrapolates his revaccination postulate. It, however, does not raise a genuine issue of material fact as to the adequacy of the package circular.

In addition to the Halsey study, *see* below at 44 n. 24, the ACIP stated "[t]here is no evidence of enhanced risk from receiving live measles vaccine in persons who have previously received live measles vaccine or had measles. *Specifically, there does not appear to be any enhanced risk of SSPE."* Recommendations of the Immunization Practices Advisory Committee, 31 *Morbidity and Mortality Weekly Report* 217, 221 (1982). At the time of Lisa's vaccination, Merck's revaccination warning was adequate in light of the then known revaccination risks, which appear to be no risk at all.

Looked at through the current state of medical evidence, Merck's MMR II revaccination warning would be

inadequate in that it does not, ironically, *recommend* revaccination. The ACIP and the Redbook Committee now recommend that all children receive two doses of measles vaccine.[25] Recommendations of the Immunization Practices Advisory Committee, *38 Morbidity and Mortality Weekly Report* S-9 (1989); Recommendations of Committee of Infectious Diseases of the American

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[25]The Redbook Committee recommendation provides:

I. Routine Vaccination

The Committee recommends two doses of measles vaccine for all children after the first birthday. In routine circumstances, the first dose should be given as measles, mumps, rubella (MMR) at age 15 months and the second also as MMR at entrance to middle school or junior high school.

Revaccination at this age appears desirable in order (1) to achieve rapid impact, since the risk of measles increases substantially soon after entrance to middle school or junior high school, (2) to boost immunity shortly before the high risk period, and (3) to reinforce possible waning immunity.

The ACIP recommendation provides "[t]here is no evidence of increased risk from live measles vaccination in persons who are already immune to measles, as a result of either previous vaccination or natural disease." *Morbidity* at 12

Academy of Pediatrics, "Measles: Reassessment of the Current Immunization Policy," at 6, excerpt attached as exhibit A of the affidavit of Christopher M. Martin, M.D. Dr. Geraghty's opinion, standing alone in the field as it does without any supporting documentation, is not sufficient to create an issue of fact to defeat a motion for summary judgment which is amply buttressed by contrary medical evidence.

It follows that Merck's motion for summary judgment must be granted because Merck's MMR II package circular is adequate as a matter of law and it was made available to Nurse Frederick, who was a learned intermediary. Therefore, Merck did not breach its duty to warn.

IV. CONCLUSION

In summary, Merck must be awarded summary judgment in its favor on all of the Mazurs' claims because it exercised reasonable care to see that the Mazurs were informed of the risks of MMR II vaccination, either by direct notice or notice through a learned intermediary. Merck rightfully relied upon the CDC to provide vaccine recipients with the Important Information Statement. Nurse Frederick was a learned intermediary so far as the school inoculation program was concerned. The notice furnished to her was adequate. Therefore, Merck cannot be held responsible for Lisa's illness.

LISA MARIE MAZUR, a Minor, in her own right, and ANTHONY MAZUR and EDNA MAZUR, as Parents and Guardians, and in their own right, Plaintiffs,

v.

MERCK & CO., INC., Defendant

Civ. A. No. 85-6494

United States District Court, E.D. Pennsylvania.

June 29, 1990

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OPINION

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DITTER, District Judge.

Plaintiffs Lisa Marie Mazur and her parents, Anthony and Edna Mazur, claim that Lisa contracted subacute sclerosing panencephalitis ("SSPE"), a debilitating, terminal disease of the central nervous system, as a result of an inoculation with a measles, mumps, and rubella

vaccine manufactured by defendant Merck & Co., Inc. Before me is defendant's motion for summary judgment and to exclude plaintiffs' expert testimony.

The Mazurs brought this diversity action asserting claims of strict liability and negligence for both design and manufacturing defects and for failure to provide an adequate warning, breach and reckless breach of the implied warranties of merchantability and fitness for a particular purpose, intentional and negligent misrepresentation, and negligent infliction of emotional distress. They seek compensatory and punitive damages.

Merck moves for summary judgment and for exclusion of the expert testimony of plaintiffs' witnesses.[1]

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[1] Merck styles its motion as one for summary judgment. I presume that Merck intended that its motion would effectively end the litigation, at least on the district court level. I do not see it that way, however. Summary judgment on all of the Mazurs' claims would be appropriate only if I found that the extensive federal regulaton of vaccines preempted all of their claims or if I found that the Mazurs could not prove that the MMR II vaccine caused

It contends that federal regulation of vaccine manufacturing, distributing, and labeling preempts the Mazurs' tort claims in their entirety. Alternatively, Merck maintains that the tort claims of the Mazur parents are barred by the applicable Pennsylvania statute of limitations, 42 Pa. C.S.A. § 554(2) and (7). It also argues that I should find as a matter of law that it did not breach the duty to warn recipients of the vaccine of its risks.

After considering the facts presented by the parties in a light most favorable to the plaintiffs, the motion for partial summary judgment will be denied in part. As I will explain more fully below, I find that Congress did not preempt state tort claims asserted by a victim of an adverse reaction to a Food and Drug Administration–approved vaccine. A reasonable jury could find for either side on the

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Lisa's injuries. If not, there are some claims, such as the design defect charge, that were not addressed by the parties in their briefs and remain viable. Therefore, I will treat Merck's motion as one for partial summary judgment.

statute of limitations issue. However, I will reserve judgment on the question of whether Merck has shown as a matter of law that it did not breach its duty to warn of the dangers associates with the vaccine.

I. FACTS

In response to a measles epidemic among school children in Philadelphia in the late 1970's, the City of Philadelphia, Department of Public Health ("Health Department") proposed a regulation that would require all children attending any school in Philadelphia to be vaccinated against certain pediatric diseases as a condition of continued school attendance. Affidavit of Robert G. Sharrar, M.D. ¶4, attached as Merck's exhibit B ("Sharrar aff."). The School Board of Health adopted the regulation and authorized the Health Department to exclude any student in kindergarten through twelfth grade from any Philadelphia school, public or private, if he or she was not

vaccinated against measles, mumps, rubella, polio, diphtheria, and tetanus or had not naturally acquired immunity by having the disease. Sharrar aff. at ¶5. School nurses were instructed to review the health records of approximately 300,000 students to determine the vaccines each one needed, if any, and to obtain written permission from parents to have their child vaccinated. *Id.* at ¶15. Parents were required to document previous immunizations or prior illnesses. If adequate proof was not forthcoming, the child was considered unimmunized and was later vaccinated. *Id. at ¶16.*

The Health Department, through Dr. Sharrar, contacted the United States Center for Disease Control ("CDC") of the Department of Health and Human Services for assistance in designing a program for the children. *Id.* at ¶7. Following a recommendation of the CDC, Dr. Sharrar decided that combined vaccines would be used in the inoculation program. He chose MMR II ("MMR II") as

the vaccine for the simultaneous immunization against measles, mumps, and rubella. *Id.* at ¶8.

MMR II is manufactured by Merck under a license from the Food and Drug Administration ("FDA"). MMR II is a live virus vaccine or immunization against all three childhood diseases. The measles portion of MMR II contains an attenuated line of measles virus, which when injected into the body causes it to generate antibodies to ward off a measles infection. MMR II is packaged in containers which include an insert describing the risks associated with the vaccine's use. The April, 1981, package insert contained the following pertinent information about the risk of contracting SSPE from the MMR II vaccine.

> There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccination distribution, the association of

> SSPE cases to measles vaccination is about one case per million vaccine doses distributed. this is far less than the association with natural measles, 5–10 cases of SSPE per million cases of measles. The results of a retrospective case–controlled study conducted by the Center for Disease Control suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with its inherent risk of SSPE.

According to the package circular, the vaccine is indicated for immunization "in children 15 months of age or older, and adults." Additionally, it included the following paragraph about revaccination:

> Based on available evidence, there is not reason to routinely revaccinate children originally vaccinated when 12 months of age or older; however, children vaccinated when younger than 12 months of age should be revaccinated. The decision to revaccinate should be based on evaluation of each individual case.

The FDA approved the package circular before it was included with the vaccine. Affidavit of William B. Freilich, ¶4, attached as Merck's exhibit A ("Freilich aff.").

The MMR II vaccines were purchased from Merck by the CDC at Dr. Sharrar's request. At first, Merck would not sell the vaccines to the CDC. Merck relented when the CDC contractually agreed either to assure that a physician would be present at inoculation or to provide MMR II recipients or their parents with what Merck and it believed to be an adequate warning of the risks associated with MMR II immunization.[2] Freilich aff. at ¶15. The CDC

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[2] The CDC and Merck signed three purchase contracts for the MMR II vaccines to be provided to the Health Department. Each contract contained the following language:

> [CDC], represents and agrees that it will (1) take all appropriate steps to assure that all vaccine supplied to various locations within the 50 states,...pursuant to the terms of this contract, shall be administered to each patient on the basis of an individualized medical judgment by a physician, or (2) take all appropriate steps to provide to such a patient (or to the patient's parent or guardian) meaningful warnings relating to the risks and benefits of vaccination, in form and language understandable to such patient, parent or guardian. Freilich aff. at ¶17 and

drafted an "Important Information Statement" to be sent to all parents of school age children. *Id.* at ¶22 and exhibit 6. The statement was designed to allow parents to weigh the benefits against the known risks of MMR II vaccination in a manner they would ordinarily comprehend. The Important Information Statement was sent home to parents via their children. Merck's exhibit R at 45.

Lisa Mazur, the Mazurs' fourth child, was born on August 11, 1969. Lisa's medical history prior to 1982 was for the most part unremarkable. Lisa's three siblings all had measles and German measles (rubella) prior to Lisa's birth. Mazurs' exhibit 2 at 59. On October 11, 1973, Lisa received a measles vaccine and a German measles vaccine from her private physician. Prior to February, 1982, Lisa had not received a mumps vaccine and had not naturally acquired immunity to the mumps. From late 1979 through

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exhibits 3, 4, and 5.

January, 1982, Lisa was treated on a number of occasions for colds, a sore throat, allergies, and pharyngitis. On January 8, 1982, Lisa underwent a tonsillectomy. During that time, she was a student at the Morrison School in Philadelphia.

Mrs. Mazur claims that she never received the Important Information Statement or any other warning about the risks of MMR II inoculation. Yet, she admits that she saw two documents apprising her of the immunization program. Mazurs' exhibit 2 at 106–108. One of the two documents she received was a letter from the School District with an attached student immunization record and parental permission form. Mazurs' exhibit 10. The letter explains the immunization program and what each parent must do either to allow inoculation or to prevent it. *Id.* Mrs. Mazur states that she read the letter and permission form but refused to sign it or return it unsigned to the school. Mazurs' exhibit 2 at 109. In any

event, upon learning of the immunization program. Mrs. Mazur called the school principal and the Board of Education to inform them that Lisa had received a measles vaccine in 1973 and to protest any revaccination.[3] Mazurs' exhibit 2 at 109–21. As a precaution, Mrs. Mazur kept Lisa out of school for approximately a week before sending her back just prior to the day of the immunization program at Lisa's school. *Id.* at 117. Mrs. Mazur claims that she did not provide written or oral permission for Lisa to receive the MMR II vaccination. Nevertheless, Lisa received an MMR II vaccine shot on February 26, 1982.

On September 7, 1983, Lisa was admitted to St. Christopher's Hospital for Children in Philadelphia for tests because of "personality changes in the past six months with abnormal movements in the past few weeks." Mazurs'

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[3] As a result of the fact that the MMR II vaccine is a combined vaccine, Lisa would receive a second dose of measles and rubella virus.

Exhibit 14. After reviewing Lisa's electroencephalogram results, one of her doctors stated that SSPE should be "seriously consider[ed]" as a cause of her physical and behavioral problems.[4] Mazurs exhibit 14. In late September, 1983, Lisa's doctors at St. Christopher's made a "presumptive" diagnosis of SSPE. Mazurs' exhibit 15. On November 2, 1983, another doctor, who examined Lisa at her parents' request, agreed with the earlier diagnosis of SSPE.

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[4] SSPE is a fatal, slowly progressing, inflammatory disease of the central nervous system. SSPE most often strikes children between the ages of four and twenty. The onset of the disease is marked by insidious mental deterioration and psychological disturbances. Neurological and motor dysfunctions such as convulsions, seizures, visual difficulties, and myoclonic jerks are often seen. In its final stages, SSPE causes increased mental and physical decline which often leaves the patient incapacitated. Death usually occurs within one to three years. *See, e.g., The Merck Manual*, 2041 (Merck Sharp & Dohme Research Laboratories), 15th ed. 1987); *Harrison's Principals of Internal Medicine*, 2096 (R. Petersdorf, 10th ed. 1983).

II. PREEMPTION

Merck contends that the pervasive scheme of federal regulation governing the production, labeling, and distribution of vaccines impliedly preempts the Mazurs' Pennsylvania tort claims for breach of the duty to warn recipients of a vaccine of its hazards. The concept of preemption has its roots in the supremacy clause of the Constitution, art. VI, cl. 2. There are two types of preemption: express and implied. *Hillsborough County v. Automated Medical Laboratories,* 471 U.S. 707, 105 S.Ct. 2371, 85 L.Ed.2d 714 (1985).[5]

[1] Implied preemption may arise in either of two ways. First, Congress may indicate an intent to occupy an entire field of regulation, in which case the states must leave all regulatory activity in that area to the federal government. *Fidelity Federal Savings & Loan Assoc. v. De*

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[5] Merck makes no claim that Congress expressly preempted state tort law.

la Cuesta, 458 U.S. 141, 102 S.Ct. 3014, 73 L.Ed.2d 664 (1982). Second, Congress may preempt state law to the extent that state law actually conflicts with federal law. Such a conflict arises when compliance with both federal and state law is impossible or when state law frustrates the purposes of federal law. *Michigan Canners and Freezers Assoc. v. Agricultural Marketing and Bargaining Board*, 467 U.S. 461, 104 S.Ct. 2518, 81 L.Ed.2d 399 (1984).

There is no question that federal regulation of vaccines, such as MMR II, is comprehensive. MMR II is subject to the provisions of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §301 *et seq*, and the Public Health Service Act ("PHSA"), 42 U.S.C. §215 *et seq*. Both regulations govern nearly every aspect of vaccine testing, design, production, labeling, and distribution. For example, each vaccine manufacturer must file with the FDA a detailed application for a license to begin testing a new vaccine, inform the FDA of production and distribution

plans, and if approved, complete periodic updates containing a broad spectrum of information. 21 C.F.R. §600 *et seq.* Similarly, the vaccine label and package circular must receive federal approval. 21 C.F.R. §§ 1, 201. The FDA requires extensive information to be included on the label and package circular, such as the composition of the vaccine, the expiration date, the storage directions, the indications and contraindications of vaccine usage, and the potential adverse reactions. 21 C.F.R. §§ 610.60–610.65. The language of the label and package circular is subject to FDA scrutiny and cannot be changed without FDA authorization. 21 C.F.R. §601.12.

[2–4] Preemption of state tort law, however, does not automatically follow extensive federal regulation. *Hillsborough*, 471 U.S. at 715, 105 S.Ct. at 2376. Vaccine regulation, like the regulation of other prescription products, is primarily, but not exclusively, a federal concern. State regulation of these products plays an important and

legitimate role and should not be displaced unless exceptional circumstances warrant it. In other words, in the absence of express preemption, there is a strong presumption that Congress did not intend to displace state law. *Maryland v. Louisiana*, 451 U.S. 725, 726, 101 S.Ct. 2114, 2118, 68 L.Ed.2d 576 (1981).[6] Moreover, this presumption against preemption is even stronger when state

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[6] In *Hillsborough*, the Court explained that:

> because agencies normally address problems in a detailed manner and can speak through a variety of means...we cane expect that they will make their intentions clear if they intend for their regulations to be exclusive. Thus, if an agency does not speak to the question of pre-emption, we will pause before saying that the mere volume and complexity of its regulations indicate that the agency did in fact intend to preempt.

471 U.S. at 715, 105 S.Ct. at 2376.

regulation of matters related to health and safety is involved, *Hillsborough*, 471 U.S. at 715, 105 S.Ct. at 2376, and when federal regulation would work to preempt state tort remedies, *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251, 104 S.Ct. 615, 623, 78 L.Ed.2d 443 (1984). Here, if federal regulation of vaccines is exclusive, Pennsylvania's ability to best protect its citizens from the dangers of vaccine use is severely hampered and it leaves those Pennsylvania citizens harmed by vaccines without a state tort remedy. Hence, I agree with the great majority of courts addressing this issue that Congress did not impliedly preempt state regulation of vaccine manufacture, distribution, and labeling.[7]

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[7] *See, e.g., Hurley v. Lederle Laboratories Division of American Cyanamid Co.*, 863 F.2d 1173 (5th Cir. 1988), *rev'g Hurley v. Lederle Laboratories*, 651 F. Supp. 993 (E.D.Tex.1986); *Abbot v. American Cyanamid Co.*, 844 F.2d 1108 (4th Cir.), *cert denied* 488 U.S. 908, 109 S.Ct. 260, 102 L.Ed.2d 248 (1988), *rev'g* 1988 U.S. Dist. Lexis 14355 (E.D. Va. 1987); *Jones by Jones v. Lederle Laboratories*, 695 F. Supp. 700 (E.D.N.Y. 1988); *Foyle by*

Merck's preemption argument is further diluted by the National Childhood Vaccines Injury Act of 1986 ("NCVIA"), 42 U.S.C. §§ 300aa-33. The NCVIA clearly shows that Congress intended state tort remedies to remain in effect despite extensive federal regulations. The NCVI was enacted to provide an alternative to the courts for the redress of vaccine-related injuries. The NCVIA established a fund from which individuals injured by vaccines may receive compensation if certain statutory requirements are met. The NCVIA does not eliminate, however, the state tort system as an avenue of redress. It has numerous references to the state tort system and expressly provides that "[s]tate law shall apply to a civil action brought for

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McMillan v. Lederle Laboratories, 674 F.Supp. 530 (E.D.N.C.1987); *Martinkovic v. Wyeth Laboratories, Inc.*, 669 F.Supp. 212 (N.D. Ill.1987); *Morris v. Parke, Davis & Co.*, 667 F.Supp. 1332 (C.D.Cal.1987); *MacGillvray v. Lederle Laboratories*, 667 F.Supp. 743 (D.N.M. 1987); *Graham v. Wyeth Laboratories*, 666 F.Supp. 1483 (D.Kan.1987); *Patten v. Lederle Laboratories*, 655 F.Supp. 745 (D.Utah 1987).

damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a). Similarly, it provides that:

> [n]o state may establish or enforce a law which prohibits an individual from bringing a civil action against a vaccine manufacturer for damages for a vaccine-related injury or death...

Id. at § 300aa-22(e). These sections certainly manifest Congress' intent to preserve traditional state tort remedies for redress of injuries related to vaccine use.

Merck argues alternatively that even if federal regulations do not preempt state regulation of vaccine labeling generally, I should find that Congress intended to preempt the more narrow field of "state regulation of the information to be provided to the medical community regarding the ... association between the administration of measles vaccine and SSPE." Merck's mem. in sppt. at 52. Merck suggests that preemption is intended because during the mid-1970's the CDC studied the relationship, if any, between measles vaccines and SSPE. The results of the

study, published in *Morbidity and Mortality Weekly Report*, 359–60 and 365 (November 19, 1976), were then sent to Merck by the FDA with the "suggest[ion] that you review your package circular ... and revise ...[it] ... appropriately to reflect these modifications of earlier recommendations." Mazurs' exhibit 54.

[5] I have no doubt that because of this prodding by the FDA, Merck's package circular reads as it does; however, mere compliance with an FDA suggestion, or for that matter, regulation or order, does not mean that state tort law becomes irrelevant. First, compliance with an FDA regulation may establish that the manufacturer met the appropriate minimum standards of due care, but compliance does not necessarily absolve the manufacturer of all liability. *See, e.g., Brochu v. Ortho Pharmaceutical Corp.*, 642 F.2d 652, 658 (1st Cir.1981). Manufacturers must meet state safety requirements, whether codified or embodied in

the common law, in addition to satisfying the initial FDA requirements.

Second, federal regulation serves a very different purpose than state tort law. Essentially, federal regulation serves a deterrent purpose by limiting the manufacture of inherently dangerous products to those applicants who meet certain stringent safety standards, while state tort law serves the equally important purpose of compensating individuals injured by those very same products. Since compliance with FDA regulations will not ensure that a manufacturer's products will not cause injury, compliance will not necessarily exempt a manufacturer from liability. When those products do cause injuries, the state tort system provides a means of compensation. State tort law is intended to supplement federal regulation by providing a vehicle for compensation of vaccine-related injuries.[8]

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[8] The Commissioner of Food and Drugs at the FDA disavowed any intention to preempt state tort law with its

[6] Merck also contends that federal regulation of vaccine labels and package circulars would be undermined if state law required that they contain different information than that already approved by the FDA. Merck cites *Cippolone v. Liggett,* 789 F.2d 181 (3d Cir.1986), *cert. denied,* 479 U.S. 1043, 107 S.Ct. 907, 93 L.Ed.2d 857 (1987), for its two-pronged analysis of when state law so conflicts with federal law as to require that state law yield.[9]

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labeling rules. "It is not the intent of FDA to influence the civil tort liability of the manufacturer or of the physician. Rather, it is the agency's intent to ensure that a complete and accurate explanation of the drug is provided to the medical community." *Bansemer v. Smith Laboratories, Inc.,* 1988 U.S. Dist. Lexis 16208, 16215 (E.D.Wis. September 12, 1988) quoting 44 Fed.Reg. 37,437 (1979)). *See also* 43 Fed.Reg. 4214 (January 31, 1978).

[9] *Cippolone* is a good example of when preemption is intended. In *Cippolone,* the Third Circuit focused on the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1331 *et seq.* That Act prescribed the exact wording of the label to be placed on cigarette packages and included a preemption provision which precluded state legislatures from requiring warnings on cigarette packages which differed from those mandated by the Act. There is no such provisions in the FDCA or PHSA. *See In re Tetracycline*

The analysis begins with a determination of the purposes of federal law. The Court should next determine whether a state law would frustrate the purposes of federal law. *Id.* at 187. Using this analysis, I once again hold that no finding of preemption is warranted.

I accept, for the sake of argument, Merck's contention that the purpose behind FDA regulation of labeling is uniformity.[10] But if a state jury determines that Merck should have disclosed more information regarding the causal link between SSPE and MMR II, if in fact there is one, *see infra* at 263, Merck can petition the FDA to allow it to change its package insert. 21 C.F.R. §601.12. Thus, Merck could meet both federal and state law requirements. Moreover, it makes sense from a policy

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Cases, 1989 U.S. Dist. Lexis 4130, 4143–45 (W.D.Mo. March 29, 1989).

[10] I disagree with this contention, but I see no reason to belabor the issue. I suggest that a concern for the safety of consumers plays a more vital role.

standpoint to permit civil judgments to supplement federal regulations. As the Court of Appeals for the District of Columbia noted in the related area of herbicide regulation by the Environmental Protection Agency ("EPA"):

> successful actions of this sort may lead manufacturers to petition EPA to allow more detailed labelling of their products; alternatively, EPA itself may decide that revised labels are required in light of new information that has been brought to its attention through common law suits. In addition, the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.

Ferebee v. Chevron Chemical Co., 736 F.2d 1529, 1542–43 (D.C. Cir.), *cert. denied* 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984)[11]. Rather than working at odds with

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[11] In the *Tetracycline Cases,* the Court raised a similar point. The Court posited that the common law duty to warn carried with it a duty to seek FDA approval of additional warnings. *In re Tetracycline Cases,* 1989 U.S. Dist. Lexis at 1448. The Court further opined that "[t]o fund otherwise would allow a manufacturer, having learned

each other, federal regulation and state common law acting in concert can improve vaccine safety of existing vaccines and spur the development of improved vaccines.

Accordingly, I find Pennsylvania tort law is not preempted by federal regulation of vaccine manufacture, distribution, and labeling, in general, and with respect to SSPE information in the package circular, in particular. Therefore, Merck's motion for partial summary judgment on this ground will be denied.

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of additional side effects or precautions, to escape liability for injuries resultant therefrom by remaining silent and relying on lack of prior FDA approval." *Id.; see also MacGillvray v. Lederle Laboratories,* 667 F.Supp., 743, 745 (D.N.M.1987) ("Public policy militates against finding as a matter of law that FDA approval of a particular drug product relieves a pharmaceutical company of further responsibility to continue research and testing to develop safer products.").

III. STATUTE OF LIMITATIONS

Lisa Mazur received the MMR II vaccination on February 26, 1982. The Mazurs filed this action on October 31, 1985. Merck contends that the tort claims of Lisa's parents are barred under Pennsylvania's two-year statute of limitations.[12] 42 Pa. C.S.A. § 5524(2) and (7). Ordinarily, the two-year statute would be a bar to this action; however, Mr. and Mrs. Mazur may be entitled to invoke the "discovery rule" in order to extend the period of limitations. *Urland v. Merrell-Dow Pharmaceuticals*, 822 F.2d 1268 (3d Cir.1987).

[7,8] Where an injured person is unable, "despite the exercise of diligence, to determine the injury or its cause," the discovery rule tolls the running of the statute of limitations. *Pocono International Raceway, Inc. v. Pocono*

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[12] The running of the statute of limitations as to Lisa's tort claims is tolled during her minority. 42 Pa. C.S.A. § 5533(b) (1984).

Produce, Inc., 503 Pa. 80, 84, 468 A.2d 468, 471 (1983). The rule provides that the limitations period begins to run when the plaintiff knows or should know: (1) that he has been injured, and (2) the injury has been caused by another party's conduct. *Cathcart v. Keene Industrial Insulation*, 324 Pa.Super. 123, 135–37, 471 A.2d 493, 500 (1984). The proverbial clock starts to tick when the injured party "possesses sufficient critical facts to put him on notice that a wrong has been committed and that he need investigate to determine whether he is entitled to redress." *Zeleznik v. United States*, 770 F.2d 20, 23 (3d Cir.1985), *cert. denied*, 475 U.S. 1108, 106 S.Ct. 1513, 89 L.Ed.2d 913 (1986). With respect to this case, the salient issues are (1) when did Mr. and Mrs. Mazur know, or when should they have known that Lisa had SSPE; and, (2) when did they know, or when should they have known, that MMR II was the

cause of the disease.[13] As to both questions, on the record before me, I conclude that genuine issues of material fact require resolution at trial.

The parties' submissions create an issue of fact as to when Lisa's parents knew of the SSPE diagnosis. On the one hand, in late September, 1983, Lisa's doctors, after reviewing the results of a broad range of diagnostic tests, discharged her from St. Christopher's with a diagnosis of "presumptive subacute sclerosing panencephalitis." Mazurs' exhibit 15. The consultation reports filled out by the numerous doctors who examined Lisa in September all include SSPE as a possible, if not probable, cause of Lisa's illness. *Id.* Additionally, Mrs. Mazur acknowledges in deposition that a Dr. Foley at St. Christopher's told her at some unspecified time that Lisa had SSPE. Merck's exhibit

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[13] Of course, the issue of whether the MMR II vaccine caused the disease has not been resolved. *See infra* at 263. I am merely assuming causation for this limited purpose.

D at 141. Each of these facts tends to show that the Mazurs knew or should have known that Lisa had SSPE before October 31, 1983. On the other hand, the discharge summary and many of the consultant's reports include other possibilities for Lisa's illness, such as "Leigh's encephalopathy or seizure disorder." Mazurs' exhibit 15. In his deposition, Lisa's treating physician, Dr. Warren Grover, stated that the term "presumptive" implied that the diagnosis was not final. Mazurs' exhibit 52 at 14. At the Mazurs' request, a second doctor, Samuel H. Tucker, M.D., confirmed the "presumptive" SSPE diagnosis in a letter dictated on October 28, 1983, and dated November 2, 1983. Mazurs' exhibit 17. It is unclear when the Mazurs were informed of this confirmatory opinion. The discharge summary, dated December 21, 1983, of Lisa's November visit to St. Christopher's includes the first unqualified diagnosis of SSPE. Mazurs' exhibit 18. When all the facts are examined, it seems that until then, at best, Lisa's doctors

believed that in all likelihood she had SSPE but they could not make a definite statement to that effect.

The Mazurs contend that they cannot be held to a higher standard of knowledge than Lisa's doctors. They argue that if the medical personnel who saw Lisa could not come to a definitive conclusion about her illness until November, 1983, it would be unfair to presume that the Mazurs, who are not experienced in the medical field, knew or should have known that she had SSPE before October 31, 1983. This argument finds support in the Pennsylvania case of *Trieschock v. Owens Corning Fiberglas Company,* 354 Pa.Super. 263, 511 A.2d 863 (1986), *alloc. denied,* 514 Pa. 617, 521 A.2d 932 (1987). In that case, as part of a routine medical check-up conducted by his employer in March, 1982, Trieschock was told by the company doctor that he was suspected of having asbestosis. On April 8, 1982, that diagnosis was confirmed by an independent

specialist. Trieschock filed suit on April 6, 1984. The Court opined that:

> [a] plaintiff in a creeping disease case should not be required to have greater knowledge than his physicians about his medical condition. If those physicians are not reasonably certain as to his diagnosis, then he certainly cannot be bound to have the knowledge necessary to start the statute of limitations running.

354 Pa.Super. at 268, 511 A.2d at 866. Here, it is possible that Lisa's doctors could not identify her illness with a reasonable degree of certainty until early November, 1983. It may be that upon further examination of the facts at trial, a jury could conclude that the Mazurs knew in September or October, 1983, that Lisa had SSPE.

A reasonable jury could also find that the "presumptive" diagnosis of SSPE triggered a duty of diligent investigation as to the cause of Lisa's illness which went unfulfilled, thereby preventing the application of the discovery rule to toll the running of the limitations period.

However, the request that Dr. Tucker examine Lisa to confirm or refute the SSPE diagnosis might satisfy the requirement of diligent investigation. Additionally, on the scant record before me it is unfair to conclude that the Mazurs knew or should have known the nature of Lisa's ailment before it was ascertained with a reasonable degree of certainty by the medical profession.

Even assuming *arguendo* that Lisa's parents knew that she had SSPE before October 31, 1983, Merck's motion for partial summary judgment on the basis that the statute of limitations ran still must be rejected. There is a genuine issue of material fact as to whether Mr. and Mrs. Mazur knew or should have known that Lisa's SSPE was caused by the MMR II inoculation. As I will discuss in greater detail below, *see infra* at 263, the causation question is unresolved. Even the so-called experts cannot agree on the cause of Lisa's illness after six and a half years of investigation. Once again, I will not hold Mr. and Mrs.

Mazur accountable to a greater standard of understanding of their daughter's illness than her doctors.

Nonetheless, the contention that the Mazurs knew of the relationship between SSPE and measles, and quite possibly, the MMR II vaccine, is not without merit. On September 29, 1983, three days after Lisa was first discharged from St. Christopher's, Nancy Wasser, Esquire, then associated with the law firm of Sprague and Rubenstone, now Sprague, Higgins, Creamer & Sprague, the Mazurs' present counsel, contacted the nurse, Jeanette W. Fairorth, at the school where Lisa was enrolled.[14] Affidavit of Jeanette W. Fairorth, ¶ 4, attached as Merck's

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[14] Ms. Wasser avers that she was not retained as counsel by the Mazurs and only contacted the school nurse as a friend of the family. Affidavit of Nancy Wasser, ¶ 5, attached as Mazurs' exhibit 53. Lisa's older sister, Deborah, was employed by Sprague & Rubenstone as a legal secretary. *Id.* at ¶3. However, Ms. Wasser apparently identified herself to Ms. Fairorth as an attorney in Sprague's office rather than as a family friend. Fairorth Aff. at ¶4 and exhibit A.

exhibit Y. ("Fairorth aff."). On that day, Ms. Fairorth entered the following information on Lisa's health records:

> T-C from Nancy Wasser "Attorney Spragues' [sic] office. Wanted info re measles shot date. Apparently Lisa is ill. Conf [with] vice principal Ms. Castleberry. Lisa's sister will come in for copy of immunization card. Med record from Creighton not in pocket.

Fairorth aff. at ¶ 4 and exhibit A. This exchange certainly shows that someone in the Mazur family thought there might be a relationship between Lisa's SSPE and her measles shot. Whether this conversation shows that for statute of limitations purposes the Mazurs knew or should have known of the causal link between SSPE and MMR II is an issue that must be left for a jury to decide. It very well may be that upon an examination of the circumstances surrounding this phone call that a reasonable jury could conclude that Mr. and Mrs. Mazur did, in fact, know of the causal relationship between Lisa's SSPE and MMR II inoculation. Then again, a reasonable jury could also

conclude that the phone call was merely part of the family's comprehensive efforts to gather information relating to Lisa's medical history. Because there are genuine issues of material fact relating to Merck's contention that the Mazur parents' tort claims are barred by the statute of limitations, I will deny Merck's motion for partial summary judgment on that ground.

III. DUTY TO WARN

A. The Parties' Contentions

The Mazurs charge Merck with failing to warn them of the risks associated with the MMR II vaccine before Lisa was inoculated. They allege that they never received any warning from either Merck or the school before Lisa was vaccinated.[15] The Mazurs assert claims of strict liability

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[15] Mrs. Mazur states in her deposition that Lisa did, in fact, bring home two documents, but not the Important Information Statement, that informed her of the schedule dimmunization program at the Morrison School. Merck's

and negligence for failure to warn. The Mazurs' duty to warn claims depend on proof of four facts: (1) Merck had a duty to warn Lisa or her parents of the health hazards associated with MMR II use; (2) Merck breached that duty; (3) Merck's breach proximately caused Lisa's injuries; and (4) Merck's breach actually caused Lisa's injuries.

In its defense, Merck argues that it did not have a duty to warn the Mazurs, but it needed to warn only Dr. Sharrar, who decided that the MMR II vaccine would be used, or some other "learned intermediary." *See Reyes v. Wyeth Laboratories*, 498 F.2d 1264, 1276 (5th Cir.), *cert. denied*, 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974). It also maintains that the warning it provided to

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exhibit D at 104–05, and Mazurs' exhibit 2 at 106–108. Mrs. mazur admits that she read the letter and permission form but refused to sign it or return it to the school unsigned. *Id.* at 109. Whatever Mrs. Mazur saw, it was apparently enough of a warning to cause her to protest Lisa's pending vaccination to the principal and the Board of Education and to keep Lisa out of school for a week as a precaution. *Id.* at 117.

Dr. Sharrar was adequate as a matter of law, so it could not have breached the duty to warn. In the alternative, Merck contends that even if it had a duty to warn the Mazurs directly, that duty was adequately fulfilled by the CDC when it issued the Important Information Statement to parents of potential vaccine recipients. As for proximate causation, Merck posits that Dr. Sharrar's reliance on a CDC recommendation and on his own research absolves Merck of causal liability. Finally, Merck argues that under no circumstances can the Mazurs prove that MMR II caused Lisa to contract SSPE. After considering the parties' lengthy briefs on these issues, I find that Merck's motion for partial summary judgment on the duty to warn claims must be denied.

B. The Manufacturer's Duty To Warn

[9] Ordinarily, Pennsylvania follows Section 402A of the Restatement (Second) of Torts which imposes

strict liability on the manufacturer of a product sold "in a defective condition unreasonably dangerous to the user or consumer..." *Incollingo v. Ewing,* 444 Pa. 263, 287, 282 A.2d 206, 219 (1971). The product may be considered in a defective condition if it is sold without a warning of the hazards associated with its use. *Incollingo,* 282 A.2d at 219. The strict liability rules for prescription drug products, such as vaccines, are somewhat different under Pennsylvania law. In *Incollingo*, the Court found that there are some products "which ... [are] ... incapable of being made safe for ... [their] intended use, such as new or experimental drugs, as to which ... there can be no assurance of safety, but ... the marketing and use of the drug notwithstanding a medically recognizable risk" is justified.[16] *Id.* With respect to those special products, the

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[16] In *Incollingo,* the Court held that Chloromycetin, a broad spectrum antibiotic, fell whthin this category of "unavoidably unsafe products." *Id.* (quoting, Section 402A, comment K Restatement (Second) of Torts). MMR II,

assuming that it was properly prepared and accompanied by a proper warning, is also within this category of unavoidably unsafe products. This is evidenced by comment k of Section 402A, which provides in pertinent part:

> Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are expecially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician... The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate

ordinary, strict liability principles of Section 402A do not apply. *Id.* Rather, "the standard of care required is that set forth in § 388 of the *Restatement* dealing with the liability of a supplier of a chattel known to be dangerous for its intended use. Under this section, the supplier has a *duty to exercise reasonable care* to inform those for whose use the article is supplied of the facts which make it likely to be dangerous".[17] *Id.* 282 A.2d at 219 n.9 (emphasis added);

> consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

[17] Section 388 of the *Restatement (Second) of Torts* provides in pertinent part:

> One who supplies directly or through a third person a chattel for another to use is subject to liability to those whom the supplier should expect to use the chattel with the consent of the other or to be endangered by its probable use, for physical harm caused by the use of the chattel in the manner for which and by a person for whose use it is supplied, if the supplier

see also Baldino v. Castagna, 505 Pa. 239, 244, 478 A.2d 807, 810 (1984). If the manufacturer can show that he has met this standard of care, he cannot be held strictly liable for the injuries which his product causes. With respect to this case, where the Mazurs do not identify any design or manufacturing defect, the focus must be on whether MMR II was distributed with a proper warning. Since the Mazurs assert that Merck is both strictly liable and liable for its negligence in failing to warn them of the dangers of MMR II inoculation, a liability analysis under either theory will depend on whether Merck complied with the "duty to

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(a) knows or has reason to know that the chattel is or is likely to be dangerous for the use for which it is supplied, and

(b) has no reason to believe that those for whose use the chattel is supplied will realize its dangerous condition, and

(c) fails to exercise reasonable care to inform them of its dangerous condition or of the facts which make it likely to be dangerous.

exercise reasonable care to inform" the Mazurs of health risks associated with MMR II use.[18]

[10] In Pennsylvania, as in most other states, the manufacturer of prescription drugs or vaccines, must meet its informational obligation, in most instances, by providing an adequate warning to a "learned intermediary," *Reyes v. Wyeth Laboratories,* 498 F.2d 1264, 1276 (5th Cir.), *cert. denied,* 419 U.S. 1096, 95 S.Ct. 687, 42 L.Ed.2d 688 (1974), rather than to the general public or individual consumer. *Incollingo*, 282 A.2d at 220 (learned intermediary is the prescribing physician); *see also Walker v. Merck & Co., Inc.,* 648 F.Supp. 931 (M.D.Ga.1986), *aff'd without op.,* 831 F.2d 1069 (11th Cir.1987) (school nurse qualifies as a learned intermediary). The so-called "learned intermediary rule" embodies the practical realities

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[18] Section 388 is ordinarily applicable to negligence cases, as well as to strict liability cases involving prescription drug products. *Incollingo*, 282 A.2d at 219, n. 9.

surrounding the dispensation of prescription drugs. In such instances, the choice of which, if any, prescription product to use is:

> essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of his patient's needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient.

Davis v. Wyeth Laboratories, 399 F.2d 121, 130 (9th Cir.1968). *See also Hoffman v. Sterling Drug, Inc.*, 485 F.2d 132 (3rd.Cir.1973) (Third Circuit adopts the reasoning of *Incollingo* and *Davis* to hold that manufacturer of prescription drug need only warn either the prescribing or treating physician.). Since *Davis*, the focus has been on the extent of the medical professional's involvement in the decision to administer the drug. The learned intermediary rule has been found to apply in situations where the

medical professional exercises his "individual medical judgment bottomed on a knowledge of both patient and palliative." *Reyes*, 498 F.2d at 1276.

In most but not all of the vaccine cases, the learned intermediary rule has been applied, since a physician or a physician's aide, such as a nurse, administered the vaccine.[19] However, in *Davis*, the Ninth Circuit opined that in situations where the vaccine is not dispensed as a prescription drug and is "dispensed to all comers at mass immunization clinics without an individualized balancing by a physician of the risks involved... It is the responsibility

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[19] *See, e.g., Hurley v. Lederle Laboratories*, 863 F.2d 1173 (5th Cir.1989); *Plummer v. Lederle Laboratories*, 819 F.2d 349 (2nd Cir.), *cert. denied*, 484 U.S. 898, 108 S.Ct. 232, 98 L.Ed.2d 191 (1987); *Stanback v. Parke, Davis and Co.*, 657 F.2d 642 (4th Cir.1981); *Rohrbough v. Wyeth Laboratories, Inc.*, 719 F.Supp. 470 (N.D.W.Va.1989); *Percival v. American Cyanamid Co.*, 689 F.Supp. 1060 (W.D.Ok.1987); *Foyle by McMillan v. Lederle Laboratories*, 674 F.Supp. 530 (E.D.N.C.1987); *Walker v. Merck & Co., Inc.*, 648 F.Supp. 931 (M.D.Ga.1986), *aff'd without op.*, 831 F.2d 1069 (11th Cir.1987); *Williams v. Lederle Laboratories*, 591 F.Supp. 381 (S.D.Oh.1984).

of the manufacturer to see that warnings reach the consumer, either by giving warning itself or by obligating the purchaser to give warning." 399 F.2d at 131. All of the vaccine cases recognize the theoretical validity of the "mass immunization exception" to the learned intermediary rule, but very few have found situations where its application is warranted. *See Petty v. United States,* 740 F.2d 1428 (8th Cir.1984) (swine flu vaccine administered in a county health clinic as part of the National Swine Flu Immunization Program); *Givens v. Lederle Laboratories,* 556 F.2d 1341 (5th Cir.1977) (polio vaccine administered by private physician who testified that the "administration [of the vaccine] in his office 'really doesn't differ' from that of the Public Health Center, 'not in the administration at all.'"); *Davis (polio vaccine administered by public health official, a pharmacist, in a community clinic as part of a nationwide immunization program recommended by the Surgeon General of the United States);* Reyes (polio

vaccine administered by public health official, a registered nurse, in a community clinic as part of a nationwide immunization program recommended by the Surgeon General of the United States).

The initial step in determining if Merck must face liability for Mrs. Mazur's claim that she never received a warning is to decide whether the learned intermediary rule or the mass immunization exception applies. If the learned intermediary rule applies, Merck only need have warned adequately the learned intermediary and the failure to warn Mrs. Mazur is irrelevant. If the mass immunization exception applies, then Merck must have exercised reasonable care to see that the Mazurs, as opposed to a learned intermediary, were adequately warned. Merck chose to rely on the CDC to meet this obligation or to ensure that the learned intermediary rule would apply. It must be determined if Merck acted in accordance with its duty to exercise reasonable care to inform the Mazurs of

the health risks of MMR II use when it so contracted with the CDC. This determination will depend on whether Merck foresaw or should have foreseen that its reliance on the CDC was reasonable.

1. The Learned Intermediary Issues

[1] Merck contends that Dr. Sharrar, in his position as director of the Health Department, acted as the learned intermediary, so when Merck and the CDC provided warnings to him, it fulfilled its duty to warn the medical profession of the risks of MMR II immunization. This contention is without merit. Dr. Sharrar, in fact, did not perform the necessary individualized balancing required of a learned intermediary. There is no dispute that Dr. Sharrar considered the package circular, the recommendation of the CDC advisory committee, and the results of his own research before he selected the MMR II vaccine. Moreover, there is no dispute that Dr. Sharrar

directed school nurses to review the medical records of nearly 300,000 students in the district and that 200,000 children did not receive the vaccines for a variety of reasons. It is also undisputed, however, that *he* did not review Lisa Mazur's medical records, consider her particular susceptibilities in light of the risks of MMR II inoculation, and was not even present at the time she was immunized. Merck does not even suggest that he had ever seen Lisa Mazur, let alone examined her, before February 26, 1982. Dr. Sharrar never acted as Lisa Mazur's physician. In short, DR. Sharrar's function can be best described as purchasing agent for the Health Department. He determined what was best for the "average" student in the district and purchased enough MMR II to meet the needs of 300,000 "average" students. He did not make an individualized medical judgment about what was best for Lisa Mazur. Dr. Sharrar did not act as a learned intermediary between Merck and Lisa.

[12, 13] This conclusion does not lay to rest the learned intermediary issue. Although Merck does not argue the point directly, I fund that there is a genuine issue of material fact as to whether Ms. Edith B. Frederick, the school nurse, acted as a learned intermediary when she permitted Lisa to receive the MMR II vaccine.[20]Ms. Frederick personally reviewed the medical records of every student, including Lisa Mazur's records, at the Morrison School and determined what immunization, if any, was needed. Mazurs' exhibit 11 at 19. She sent out with each child an Important Information Statement and the School District letter with the attached immunization record and the parental permission form, and upon return of the forms made a second determination of which vaccine was

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[20] On the other hand, there is no question that Daniel S. Wood, the technician who administered the MMR II inoculation to Lisa, was not a learned intermediary. Simply put, he is not a medical professional and therefore cannot be a learned intermediary.

necessary. Merck's exhibit R at 45. She was present in the gym on the day Lisa received the MMR II inoculation. Ms. Frederick also states that one of her jobs was "to be kind of eyeballing the boys and girls to see whether they looked ill that day or if there was some reason they should not get the vaccine," and to ask if the children felt "all right." *Id.* at 49. Unfortunately, this is all the information that the parties have submitted about Ms. Frederick. Missing are affirmations of fact, such as her familiarity with the package circular or CDC recommendations, her technical training, or her memory of Lisa's condition at the time the vaccine was administered. These areas may be developed in greater detail at the time of trial. If so, a jury could conclude that she performed the traditional functions of the learned intermediary and if Merck provided her with an adequate warning, it met its burden under Pennsylvania law.

The conclusion that under certain circumstances a nurse, as opposed to a physician, can act as a learned

intermediary has won some approval, although there is no Pennsylvania case on point. In *Walker v. Merck & Co., Inc.*, 648 F.Supp. 931 (M.D.Ga.1986), *aff'd without op.*, 831 F.2d 1069 (11th Cir.1987), a case involving the administration of the MMR II vaccine to a pregnant high school student as part of a county-wide high school immunization program, the court found that under Georgia law, the learned intermediary exception applied to nurses in general, and, in particular, to the nurse who administered the vaccine. *Accord Rohrbough v. Wyeth Laboratories*, 719 F.Supp. 470 (N.D.W.Va.1989). In *Walker*, the plaintiff "received the MMR II injection from a licensed practical nurse who was aware of the risks associated with MMR II, particularly the risks for pregnant females, and who stated that she has read and understood the circular accompanying the MMR II." *Walker*, 648 F.Supp. at 934. Here, upon further examination of the facts, it may be that Ms. Frederick had a similar knowledge of the risks of MMR II

inoculation as described in the package circular and Lisa Mazur's particular needs and susceptibilities," *Davis,* 399 F.2d at 130, and she was able to make an individualized, informed medical judgment about whether Lisa should receive the MMR II inoculation.

I recognize that an argument can be made that since a Pennsylvania appellate court, *Makripodis v. Merrell-Dow Pharmaceuticals, Inc.*, 361 Pa.Super. 589, 523 A.2d 374 (1987), and a Philadelphia Common Pleas court, *Coyle v. Richardson-Merrell, Inc.*, 15 Phila. 389/1987 Phila.Cty. Rptr. Lexis 80 (Phila.Ct.Com.Pleas April 10, 1987), refused to extend the learned intermediary rule to retail pharmacists and there is no Pennsylvania case that addresses whether a nurse can act as a learned intermediary, the learned intermediary designation should be limited to physicians. A distinction can be drawn between a nurse and a pharmacist, however. The former often performs tasks similar to a physician, while the latter is more of a

technician or a retailer of previously prescribed drugs. The nurse is familiar with the patient's medical history and current condition, whereas the pharmacist is, in many instances, unfamiliar with his customer. The nurse, as well as the physician, is in a position to know the characteristics of the drug, the amount of the drug which can be safely administered, and most importantly, the individual characteristics of the patient. *Makripodis,* 523 A.2d at 378. The pharmacist only dispenses those drugs which the learned intermediary has already decided are necessary for the patient. The pharmacist often does not engage in any decision making of the kind ordinarily associated with that of doctors and nurses.

Moreover, this close association in function between doctor and nurse has been to some extent recognized by the Pennsylvania legislature in 42 Pa. C.S.A. §8334(a). Section 8334(a) extends a limited grant of immunity from liability to *both physicians and nurses* for adverse reactions arising

from the use of vaccines administered as part of a "mass immunization project."[21] This section certainly evidences a legislative view that physicians and nurses often engage in similar activities when administering vaccines on a large-scale basis. I predict that the Pennsylvania courts if presented with the question o whether a nurse can be a

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[21] There is no indication that the School District immunization was a Pennsylvania Department of Health-approved "mass immunization project." Section 8334 provides in pertinent part:

> (a) General rule. - Any physician who does not receive remuneration for his services in a mass immunization project approved in writing by the [Pennsylvania] Department of Health ..., and any registered nurse, or practical nurse licensed to practice in this Commonwealth who shall participate in such project ... shall not be liable, except for gross negligence, to any person for illness, reaction, or adverse effect arising from or out of the use of any drug or vaccine in such project by such physician or such nurse.
>
> (b) Exception. - This section shall not exempt any drug manufacturer from any liability for any drug or vaccine used in such project.

learned intermediary would recognize that doctors and nurses perform similar roles when vaccinating patients and would hold that in appropriate circumstances a nurse can act as a learned intermediary. Therefore, the issue of whether Frederick falls within the learned intermediary definition must be resolved at trial, because if so and if Merck provided her with an adequate warning, Merck did not breach the duty to warn.

2. *The Mass Immunization Exception*

Assuming *arguendo* that Ms. Frederick is not found to be a learned intermediary, the Mazurs still must prove that the mass immunization exception applies to trigger Merck's duty to warn them directly. They cannot do so, however. In *Davis*, the Ninth Circuit opined that in situations where the vaccine is not dispensed as a prescription drug and is "dispensed to all comers at mass immunization clinics without an individualized balancing by

a physician of the risks involved... It is the responsibility of the manufacturer to see that warnings reach the consumer, either by giving warning itself *or* by obligating the purchaser to give warning." 399 F.2d at 131 (emphasis added). The "mass immunization exception" has not been applied often, because as the court in *Stanback v. Parke, Davis & Co.,* 657 F.2d 642, 647 (4th Cir.1981), stated, the exception "is quite narrow and highly fact specific." I have found only four such cases, three of which dealt with nationally sponsored immunization programs: *Petty v. United States,* 740 F.2d 1428 (8th Cir.1984); Reyes; Davis; and Givens v. Lederle Laboratories, 556 F.2d 1341, 1345 (5th Cir.1977).

The mass immunization exception to the learned intermediary rule recognizes that there may be circumstances when by reason of the very size of a program, a manufacturer will know or should know that its product will not be dispenses as a prescription drug; in

short, the manufacturer can foresee that there will be no individualized balancing of the medical benefits and risks. As the court in *Reyes* stated:

> [w]here there is no physician to make an 'individualized balancing ... of the risks,' the very justification for the prescription drug exception [the learned intermediary rule] evaporates. Thus, as in the case of patent drugs sold over the counter without prescription, the manufacturer of a prescription drug who knows or has reason to know that it will not be dispensed as such a drug must provide the consumer with adequate information so that he can balance the risks and benefits of a given medication himself.

Reyes, 498 F.2d at 1276 (quoting *Davis*, 399 F.2d at 131). In *Reyes*, the court found that Wyeth "had ample reason to foresee the way in which its vaccine would be distributed," because "it was common knowledge in the drug industry that a great majority of vaccinees receive their Sabin [polio] vaccines in mass administrations or county clinics manned at least in part by volunteers ... [and] ... these clinics, as Wyeth must be presumed to know, dispense Sabin vaccine

to all comers in an 'assembly line' fashion." *Id.* at 1277 quoting *Davis*, at 131).

[14] Here, the Mazurs have not presented any facts which tend to show that Merck should have foreseen that the MMR II vaccine would have been dispensed in the Philadelphia school program without individual judgments as to each inoculation. In its contract with Merck, CDC represented and agreed that it would "take all appropriate steps to assure that all vaccine supplied to various locations within the 50 states,...pursuant to the terms of this contract, shall be administered on the basis of an individualized medical judgment by a physician ..." Freilich aff. at ¶17 and exhibits 3, 4 and 5. In fact, individualized judgments were made: two out of three students in the Philadelphia school population were eliminated from the inoculation program.

While Ms. Frederick was no physician, she was on hand when Lisa was immunized to make an individualized

decision as to each child. Even if she was inadequately trained, inadequately instructed and ultimately made the wrong decision as to Lisa, she was the school district's response to the obligation imposed on the CDC by its purchase contract with Merck. There as been no suggestion as to any reason why Merck could have or should have foreseen that the MMR II would not be dispensed as a prescription drug.

This case is distinguished from *Reyes, Davis, Givens,* and *Petty* in that the size of the immunization program here is significantly smaller and does not by its sheer size create a situation where the absence of a learned intermediary is foreseeable. In all of those other cases, the inoculation was provided to the plaintiff as part of a nationwide immunization effort. For example, in *Petty*, the vaccine was provided to the plaintiff pursuant to the National Swine Flu Immunization Program, which as one might guess from its name, was a national inoculation

drive. The recipient pool here was initially some 300,000 students in the Philadelphia school system. The Health Department program, like the program in *Walker*, was "instituted only to immunize certain ... students who needed the vaccine or who did not have their updated shot records.[22] *Walker*, 648 F.Supp. at 935. The Health Department program is simply not, for the lack of suitable substitute term, "mass" enough to fall within the narrow, highly fact specific exception to the general rule.[23]

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[22] I recognize that in all probability, the *Walker* immunization program was smaller than this one. I cannot image that Bibb County, Georgia, had nearly 100,000 high school students who received vacines as was the case with the Health Department program. Nevertheless, the two programs are more similar to each other, than to the nationwide polio or swine flu immunization programs.

[23] My decision here should not be interpreted that under no circumstances should the mass immunization exception apply to immunization programs of less than national proportion. The mass immunization exception, if it is to have any weight at all, must cover situations where the recipient pool is smaller than the whole nation. *Contra Stanback*, 657 F.2d at 647. What the size of that program should be, I will leave for others to decide. Here, I merely

As the court in *Davis* described, the polio immunization programs were for "all-comers." It does not seem that there were any provisions by which potential recipients could choose not to be immunized or by which potential recipients were rejected for some particular reason. It was as if the vaccines were dispensed as over-the-counter drugs with no means of limiting distribution to a particular individual. Here, the Health Department program allowed parents to exclude their children from the program for religious or medical reasons. *See* Mazurs' exhibit 10. Parents, if they could have proved prior immunizations or previous illnesses, could have prevented their children from being vaccinated. *Id.* As a last resort, parents also could have kept their children out of school for a period of time as a means of avoiding an unwanted immunization, as did

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conclude that a program of 100,000 recipients is not within the ambit of the exception, because its size does not create a situation where the absence of a learned intermediary is foreseeable to the vaccine manufacturer.

Mrs. Mazur. Further, school nurses excluded students by virtue of their past immunization or illness records, *id*, or by making a judgment that certain students on the day of inoculation did not appear healthy enough to receive the vaccine. Merck's exhibit R at 49. Apparently, the screening process was highly effective because nearly two-thirds of the eligible students did not receive an MMR II inoculation. In this situation, it cannot be said that the MMR II inoculation was provided to "all-comers"; rather, it was dispensed on an individual basis as needed. Because there is no evidence to suggest that Merck foresaw that no learned intermediary would be present at inoculation, the Health Department program was not large enough to be considered a mass immunization program, and the vaccine was not dispensed to "all-comers," the mass immunization exception does not apply.

3. *Adequacy Of The Package Circular*

In the event Ms. Frederick is found to be a learned intermediary, the Mazurs' challenge to the adequacy of the warnings contained the MMR II package circular that should have been provided to Ms. Frederick becomes significant. They have submitted affidavits from two doctors in support of their allegations that the package circular did not reflect accurately the dangers associated with the MMR II vaccine. Specifically, the doctors aver that the package circular substantially increased the risk that Lisa Mazur would receive an unnecessary measles vaccine because it: (1) refers to doses distributed rather than doses actually used, thereby creating the perception that the incidence rates of SSPE and measles are lower than the actual rates for the two diseases;[24] (2) does not include

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[24] The section of the April, 1981, MMR II package circular SSPE warning of which the doctors complain reads as follows:

stronger language warning intermediaries of the dangers when the MMR II vaccine is given to children medicated with Depo–Medrol, a corticosteroid; (3) fails to explain the dangers associated with revaccination; (4) states that MMR II is indicated for adult use based upon inadequate testing for adverse reactions by Merck; and (5) "demonstrates that Merck is aware of the possible causal relationship between measles vaccine and SSPE but has not properly involved itself in basic scientific research before it could say that a cause–and–effect relationship has not been determined; and thereby deemphasizes the risks involved in receiving a measles antigen in order to encourage physicians to immunize as many children as possible." Affidavits of J.

Based on estimated nationwide measles vaccination distribution, the association of SSPE cases to measles vaccination is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5–10 cases of SSPE per million cases of measles.

Anthony Morris, Ph.D., and Kevin C. Geraghty, M.D., respectively, Mazurs' exhibits 50 and 25.

[15, 16] As an initial matter, it should be noted that by receiving FDA approval of its package circular, Merck has at least complied with a minimum standard of adequacy. *See Graham v. Wyeth Laboratories*, 666 F.Supp.1483, 1499 (D.Kan.1987). Thus, it becomes incumbent upon the Mazurs to identify particular problems with the package circular. Of course, the Mazurs must also present factual support for their claims of inadequacy. Once this threshold burden is met, in ordinary circumstances, the adequacy of the warning is a question of fact for the jury, *Incollingo*, 444 Pa. at 288–89, 282 A.2d at 220; however, it is not improper for the court to determine that a warning is adequate as a matter of law. Here, I find that except for the revaccination complaint, which creates a genuine issue of material fact for trial, the

Merck package circular is otherwise adequate as a matter of law.

[17] As it appeared in the April, 1981, MMR II package circular, the revaccination section provided:

> Revaccination: Based on available evidence, there is not reason to routinely revaccinate children originally vaccinated when 12 months of age or older; however, children vaccinated when younger than 12 months of age should be revaccinated. The decision to revaccinate should be based on evaluation of each individual case.

This statement provides no information about the potential risks associated with revaccination. The Mazurs have presented evidence that revaccination poses a health risk beyond that which is covered in the circular's general SSPE warnings. Geraghty aff., Mazurs' exhibit 50. The revaccination statement discusses only the need for revaccination from an immunization standpoint without mentioning that revaccination where it is not warranted could, indeed, be harmful. Additionally, Merck fails to

distinguish the risk, if any, that may be present where a child who has been inoculated in the past with a measles vaccine, but not with one for mumps, subsequently receives the MMR II vaccine. This was the case with Lisa. She apparently received a measles and a German measles vaccine at the age of four, but never received a separate mumps vaccine. The Mazurs argue that the revaccination warning is inadequate because it fails to direct physicians to forego inoculation with MMR II altogether where a child has previously received a measles vaccine, and it fails to recommend that children who have already received one or two of the three viruses contained in MMR II be inoculated with individual vaccines to complete the trio instead of with MMR II.

Merck does not address the revaccination issue in its briefs. I can only assume, therefore, that Merck concedes the existence of a genuine issue of material fact as to the adequacy of the revaccination warning in the package

circular. The Mazurs have introduced evidence, unrefuted by Merck, from which a reasonable jury could conclude that Merck acted unreasonably by failing to specify that there are potential risks associated with inoculation with MMR II when a child has been inoculated previously with MMR II, or has been inoculated with some other form of either a measles, mumps, or rubella vaccine. Alternatively, a reasonable jury could find that the cautionary language at the end of the revaccination statement calling for "an evaluation of each individual case" is adequate to warn the medical profession about the risks, if any, of MMR II revaccination because sufficient information exists from other medical sources which refutes any relationship between revaccination and SSPE. *See* Recommendation of Immunization Practices Advisory Committee, *Morbidity and Mortality Weekly,* vol. 31, no. 17, 219–20, 221 (May 7, 1982) ("There is no evidence of enhanced risk from receiving the measles vaccine in persons who have

previously received live measles vaccine or had measles. Specifically, thee does not appear to be any enhanced risk of SSPE."). At best, the issues concerning the existence, if any, of a relationship between MMR II revaccination and an enhanced risk of SSPE and the adequacy of Merck's warnings in this regard in its package circular should be left for the jury to decide.

[18] Dr. Geraghty's accusation that Merck did not engage in sufficient research before it indicated MMR II for adult use is unavailing. I do not see the relevance of this complaint to the facts of this case. On February 26, 1982, Lisa Mazur was only twelve years old. She was not an adult. I fail to understand how the inadequate testing of adults, even if the term is defined as post-pubescent individuals as Dr. Geraghty would have it, placed Lisa Mazur at risk. The Mazurs do not claim that Lisa was even beginning puberty at that time. Dr. Geraghty does not explain why the failure to test the MMR II vaccine on

adults put Lisa at risk. Even if he is correct[25], without an explanation of how that fact would affect Lisa, I cannot conclude that the Mazurs have raised a relevant and material issue of fact as to the adequacy of the MMR II package circular.

[19, 20] The Mazurs' remaining complaints about the package circular are also without merit. The first is correct in principle, but wrong in fact. The CDC report on which Merck relied when it drafted the SSPE and encephalitis warnings was based on the results of a study that took into account the discrepancy between doses used and doses distributed in calculating the risk percentages. *Morbidity and Mortality Weekly Report*, 359–60, 365 (November 19, 1976). As for the complaint that Depo–

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[25] Current research seemingly disagrees with Dr. Geraghty. Merck referred me to a 1989 report by the CDC advisory committee in which the committee recommended that in outbreak situations junior and senior high school and college students be revaccinated. Merck's exhibit 4, attached to its reply.

Medrol should be contraindicated in the package circular, I find that the warning that patients on corticosteroids should not be vaccinated is sufficient.[26] Merck cannot be expected to identify the combined effects of an MMR II vaccine and every single medication that a child might be taking or, in this case, was taking over a month before the vaccine was administered. A reasonably prudent medical professional will understand that when the package circular contraindicates corticosteroids in general, Depo-Medrol, a specific corticosteroid, is also contraindicated.

[21] The Mazurs' claim that Merck did not engage in sufficient research before it could make the statement that a cause-and-effect relationship between SSPE and MMR II has not been determined is also fruitless. First, as can be seen below, merck does not make a statement that

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[26] The April, 1981, MMR II package circular contraindicates MMR II for use with "[p]atients receiving therapy with ... corticosteroids..."

there is no causal relationship between MMR II and SSPE. Rather, its package circular lays out the results of the CDC's comprehensive examination of the relationship of measles vaccines and SSPE.[27] Second, and most

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[27] The SSPE warning in the April, 1982, MMR II package circular is based on the findings of the CDC as reported in *Morbidity and Mortality Weekly Report*, 359–60 and 365 (November 19, 1976), and reads as follows:

> There have been reports of subacute sclerosing panencephalitis (SSPE) in children who did not have a history of natural measles but did receive measles vaccine. Some of these cases may have resulted from unrecognized measles in the first year of life or possibly from the measles vaccination. Based on estimated nationwide measles vaccination distribution, the association of SSPE cases to measles vaccinations is about one case per million vaccine doses distributed. This is far less than the association with natural measles, 5–10 cases of SSPE per million cases of

important, is that after over twenty years of study, Merck, as well as the independent researchers, have not been able either to establish or to discount a causal link between SSPE and measles vaccines. *See, e.g.,* Affidavit of Christopher M. Martin, M.D., ¶5, attached as Merck's exhibit I. Merck's and the CDC's research efforts on the causal connection between the MMR II vaccine and SSPE adequately support the statements in the package circular without deemphasizing the very real, but extremely small risk of contracting SSPE after inoculation with an MMR II vaccine.

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measles. The results of a retrospective case-controlled study conducted by the Center for Disease Control suggest that the overall effect of measles vaccine has been to protect against SSPE by preventing measles with is inherent risk of SSPE.

4. *Adequacy Of The Important Information Statement*

Because the Mazurs claim that they never received a direct warning of MMR II's dangers, rather than that they received a warning but found it inadequate in some particular way, *see, e.g., Leibowitz v. Ortho Pharmaceutical Corp.*, 224 Pa.Super.418, 307 A.2d 449 (1973), the adequacy of the Important Information Statement, as opposed to the adequacy of the package circular, *see supra* at 257, is not an issue with which I need be concerned. However the Important Information Statement was worded it had no affect on Mrs. Mazur, I will only focus on the consequences, if there are any, of Mrs. Mazur's failure to receive it.

5. *The Merck-CDC Purchase Contract*

[22-24] The Merck-CDC purchase contract provides in pertinent part that the: [CDC], represents and

agrees that it (1) take all appropriate steps to assure that all vaccine supplied to various locations within the 50 states,... pursuant to the terms of this contract, shall be administered to each patient on the basis of an individualized medical judgment by a physician, or (2) take all appropriate steps to provide to such a patient) or to the patient's parent or guardian) meaningful warnings relating to the risks and benefits of vaccination, in form and language understandable to such patient, parent or guardian.

Freilich aff. at ¶17 and exhibits 3, 4, and 5. In short, through this contract Merck attempted to guarantee that either a physician would be present at inoculation or an Important Information Statement would be sent to parents before inoculation. If the CDC performs its obligations, Merck fulfills its duty to warn under the learned intermediary rule, assuming an adequate package circular is made available to the learned intermediary, or under the mass immunization exception, because the recipient receives

an adequate warning directly.[28] The more difficult

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[28] I recognize that in Pennsylvania "the duty to provide a nondefective product is non-delegable," *Berkebile v. Brantly Helicoper Corp.*, 462 Pa. 83, 337 A.2d 893, 903 (1975) (per Chief Justice Jones, with one Judge concurring and five Judges concurring in the result), and a product sold with an inadequate warning may be considered defective. At first glance, it may seem that I am permitting Merck to delegate responsibility in a manner which contravenes *Berkebile*. However, this is not the case for two reasons. First, there is a difference between delegating responsibility to a third party and assigning a task to that third party. By obligating the CDC to provide either a learned intermediary or an Important Information Statement for the benefit of the vaccine recipient, Merck is merely assigning to the CDC the task of ensuring a particular method of distribution of its product. At all times, Merck is responsible for the CDC's *foreseeable* errors. This situation is not much different than that for any other prescription drug product. With regard to those products, the manufacturer designates them for distribution by prescription only. The manufacturer leaves it to the physician to properly prescribe the product for his patients. If the pharmacist dispenses the product without a prescription or if he dispenses it to someone who clearly should not receive it, he, not the manufacturer, is liable for his misconduct. Only if the manufacturer could foresee that the pharmacist would act in such a manner would the manufacturer be held responsible for any injuries that the product cazuses. Second, as I will discuss more fully above, section 388, the pertinent section when a prescription drug product is administered, permits, in certain circumstances, the manufacturer to escape liability by placing the obligation to warn the consumer on a third

question, which is in issue here, is what the legal consequences of the CDC's failure to live up to the demands of the contract are.

[25, 26] As I have previously pointed out, the standard of care imposed upon a manufacturer of prescription drugs is that set forth in section 388 of the Restatement. *See infra* at 252. Comment n of section 388 deals with a manufacturer's duty to exercise reasonable care to inform those who will use a product of its dangers. The comment points out that there are certain factors that will aid in a determination of whether the manufacturer has acted reasonably or not including the nature of the product, the character of the person to whom it is supplied, and the way the product will be ultimately used. The care that must be taken always increases as risk of danger increases.

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party. *See* comment n to section 388. Whether this is reasonable also depends to great extent on foreseeablity. *Id.*

Here the parties have not addressed whether Merck acted reasonably or not when it contracted with CDC to have MMR II administered only on the basis of an individualized judgment made by a physician, or only after a meaningful warning had been given to the patient or the parent. If Merck acted reasonably, it may be absolved of liability despite the fact that Lisa's parents received no notice of MMR II's dangers. Ultimately, the reasonableness of Merck's conduct may be a jury question or may be susceptible to a disposition by summary judgment. In any event, I will give the parties additional time to bring to my attention anything that they believe is relevant with regard to Merck's reliance on the contract with CDC[29]

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[29] The court in *Walker* found that as a matter of law Merck fulfilled its duty to warn when it entered into a contract identical to the one in issue here. *Walker*, 648 F.Supp. at 935. The *Walker* court relied on a proposition put forth by the court in *Reyes* and *Davis*. In those cases, the court held that a manufacturer of a vaccine could satisfy the duty to warn "by obligating the purchaser to give a warning." *Reyes*, 498 F.2d at 1276; *Davis*, 399 F.2d at 131.

The Mazurs argue that I should decide as a matter of law that the CDC did not perform its assigned tasks and Merck knew or should have known it wold not do so. they assert, therefore, that Merck did not exercise reasonable care to inform them of the risks of MMR II inoculation and must be held liable for this failure to warn.

[27] The Mazurs contend that the fact, assuming its truth, that Mrs. Mazur never received the Important

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I disagree with this statement, because it ignores the important issue of whether the manufacturer was exercising reasonable care in accordance with section 388 when he obligated the purchaser to provide the consumer with a warning. *Baldino*, 505 Pa. at 244, 478 A.2d at 807 ("a manufacturer is liable ... if he fails to exercise reasonable care to inform those for whose use the article is supplied of the facts which make it likely to be dangerous.") It may be that a vaccine manufacturer "by obligating the purchaser to give a warning" acted with reasonable care because there was no indication that the purchaser would not perform its assigned tasks. However, if obligating the purchaser to give a warning were unreasonable if, for example, it was readily apparent that the purchaser was unable to fulfill its obligation because it had no money to do so or the purchaser expressed an intention either orally or by past acts that it did not intend to perform its obligations, then the manufacturer cannot avoid liability by contract.

Information Statement from the CDC shows that Merck did not act reasonably in relying on the CDC to provide a warning to her. They are wrong. The relevant issue is not whether Mrs. Mazur actually received the Important Information Statement, but whether Merck acted unreasonably because it did not foresee that she would not receive it. The Mazurs have not presented one single piece of evidence, other than Mrs. Mazur's claim that she never saw a CDC warning, that tends to prove that the CDC was not providing warnings to parents with any degree of frequency and that Merck knew of the CDC's failure. Without something more than their self-serving allegation that they never received a warning, I will not invade the province of the jury and rule as a matter of law that Merck acted unreasonably in relying on the CDC and should be held accountable for the Mazurs' failure to receive a warning.

In summary, I extend the learned intermediary rule to cover situations where the nurse acts as a learned intermediary, but I leave for the jury the question of whether, in fact, Ms. Frederick performed the traditional duties of a learned intermediary on the day Lisa received her vaccine. I also leave for the jury the question of whether the package circular that should have been provided to Ms. Frederick adequately conveyed the risks associated with receiving a second dose of measles virus from the MMR II vaccine. Merck's contention that Dr. Sharrar acted as a learned intermediary is rejected. Further, I fund the mass immunization exception should not apply to the 1981-82 Health Department immunization program. However, I conclude that on the state of the record before me today, Merck has not shown that it acted in accordance with due care, if it had a duty to warn the Mazurs directly rather than a duty to warn Ms. Frederick, when it contracted with the CDC to provide recipients of a MMR -

II vaccine with the benefit of a physician's presence at immunization or a detailed warning of the risks of inoculation.

C. Causation

1. *Proximate Causation*

[28,30] Proof of proximate causation is one of two necessary causation elements, the other is cause-in fact, or in a tort case proceeding under theories of strict liability and negligence. *Sherk v. Daisy-Heddon*, 498 Pa. 594, 598, 450 A.2d 615, 617 (1982). A proximate cause is defined as a substantial contributing factor in bringing about the harm in question. *Van Buskirk v. Carey Canadian Mines, Ltd.*, 760 F.2d 481, 492 (3d Cir.1985). In short, the proximate causation determination is nothing more than the assignment of legal responsibility for a particular injury. In the duty to warn context, assuming that plaintiffs have established both duty and a failure to warn, plaintiffs must

further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.[30] *Van Buskirk*, 760 F.2d at 493. Defendant may "defeat causation in a failure to warn case by discrediting plaintiffs' claims that ...[the learned intermediary]... would have acted to avoid injury, or by pointing to a third party as the sole proximate cause." *Id.* at 493. In this case, Merck does not raise a significant objection to the plaintiffs' assertion that Ms. Frederick would have heeded an adequate warning, if one had been provided. Instead, Merck argues that even if it failed to provide an adequate warning to Ms. Frederick, Dr. Sharrar's

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[30] As I noted above, *see supra* at 259, because the Mazurs claim that they never received a warning, rather than that they received an inadequate warning, the Important Information Statement will be considered as adequate. Therefore, the proximate cause question relates only to the alleged inadequacy in the package circular.

reliance on non-Merck sources of information about MMR II is the true proximate cause of Lisa's illness.

[31] If Ms. Frederick is found to have acted as a learned intermediary, the important issue is whether she would have done anything different on February 26, 1982, after reading an adequate package circular. If she would no have changed her conduct and would have let Lisa receive the vaccine anyway, the causal chain is broken and Merck is absolved of liability. The record does not reveal, however, that, if anything, Frederick would have done if she had read an adequate warning. *Contra Plummer v. Lederle Laboratories,* 819 F.2d 349 (2d Cir.1987); *Stanback v. Parke, Davis and Company,* 657 F.2d 642 (4th Cir.1981) (defendant vaccine manufacturer is absolved of liability if plaintiff's treating physician testified in deposition that he was aware of the risk of illness associated with a flu vaccine, but nonetheless chose not to advise his patients about that risk before prescribing the vaccine). It may be

that Ms. Frederick would have heeded an adequate warning. I will permit the parties to supplement the record to flesh out whether a change in the revaccination warning would have caused Ms. Frederick to exclude Lisa from the immunization program.

Since it has not attempted, at this time, to discredit plaintiffs' assertion that an adequate warning would have been heeded by Ms. Frederick, Merck's asserted proximate cause defense depends on its claim that the legal responsibility for Lisa's illness should lie with Dr. Sharrar. It contends that it cannot be liable for Lisa's illness, because Dr. Sharrar relied not only on the package circular, but also on a CDC recommendation and his own independent research and medical judgment before he selected MMR II for the School District's immunization program. Sharrar aff.¶¶7 and 9. *See Schrammel v. G.D. Searle & Co.*, 1988 WL 118850, 1988 U.S. Dist. Lexis 12465 (E.D.Pa. November 4, 1988), *aff'd without op.*, 875 F.2d 311 (3d

Cir.1989) (Drug company is immune from liability if prescribing doctor had adequate information from other sources.) Merck maintains that the fact that Dr. Sharrar relied on these other sources breaks the proverbial causal chain and absolves it of any liability.[31]

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[31] This is the only intervening cause argument that Merck offers; however, it may be that Dr. Sharrar, the other School District employees, such as Ms. Frederick or Wood, or for that matter, Mrs. Mazur, negligently permitted Lisa to receive the MMR II vaccine when all indications suggested that she not receive it. Such a finding of negligence, if it had been argued by Merck, might have supported a second intervening cause contention. For example, if after reading an adequate package circular, ms. Frederick knew that Lisa should not have been inoculated for whatever reason, but, nevertheless, negligently allowed her to receive the shot, a reasonable jury could have concluded that Ms. Frederick's negligence was the substantial factor in bringing about Lisa's illness. Of paramount importance to htis determination would have been, as it so often is, the element of foreseeability. The intervening negligence would only absolve Merck of liability if it was unforeseeable to Merck at the time it sold the MMR II vaccine to the CDC for use in the Health Department immunization program. *See Neal v. Carey Canadian Mines, Ltd.,* 548 F.Supp. 357 (E.D.Pa.1982); *aff'd Van Bushirk v. Carey Canadian Mines, Ltd.,* 760 F.2d 481 (3d Cir. 1985).

[32] This argument is unavailing for purposes of summary judgment. There can be more than one proximate cause of an injury–and whether any inadequacy in the package circular was a substantial factor in causing harm to Lisa, or whether what Dr. Sharrar did or failed to do caused that harm, or both, is a jury question.

As I discussed in greater detail above, *see infra* at 260, it is an open question at this point whether Merck acted in accordance with due care when it contracted with the CDC to have the CDC provide a learned intermediary at inoculation or provide a recipient or his parents with an adequate warning. This determination depends on whether Merck foresaw that the CDC would perform its tasks. In a sense, it is a proximate cause issue. If Merck reasonably believed that the CDC would perform its assigned tasks, and it happens that the CDC did not do so, it may be that the CDC's negligence is a superseding cause of Lisa's injuries, because it is its misconduct which may be a

substantial factor in bringing about the illness. For example, if the CDC planned to meet its obligation by providing a physician at inoculation, but told the doctor to go to the wrong school, assuming the presence of the doctor would have prevented Lisa's immunization, it could be said that this negligence proximately caused Lisa's illness. I will allow the parties the opportunity to explore further this foreseeability issue.

2. *Cause-In-Fact*

[33] In order to maintain duty to warn claims against Merck, the Mazurs must establish that MMR II caused Lisa' injuries.[32] Because the subject matter of this case is of a high degree of scientific complexity, proof of

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[32] Although I address the causation question within the context of the Mazurs' duty to warn claims, that question goes to the heart of every claim the Mazurs raise. If the Mazurs cannot prove that MMR II was the cause of Lisa's injuries, all of their other cliams will also fall.

causation must be established by expert testimony. *Hamil v. Bashline,* 481 Pa. 256, 392 A.2d 1280, 1285 (1978). The Mazurs offer the testimony of two specialists in the fields of pediatrics, virology, and immunology to establish their claim the MMR II caused Lisa's injuries. Essentially, Merck raises three challenges to the Mazurs' causation evidence. The first challenge is in the form of a motion to exclude the Mazurs' proffered experts because they lack the qualifications necessary to meet the threshold admissibility standards of Federal Rules of Evidence 702. Second, Merck contends that Federal Rule of Evidence 703 bars the testimony of the two experts, if they are such, because such testimony is improvidently based upon evidence that is not reasonably relied upon by experts in their respective fields. Third, Merck argues that even if admissible, the Mazurs' proferred expert opinion testimony does not demonstrate the existence of a genuine issue of material fact as to causation.

[34] Kevin C. Geraghty, M.D., is a physician certified in pediatrics and allergy and immunology, and J. Anthony Morris, Ph.D., is a specialist in bacteriology and virology. Both men opine that the MMR II vaccine caused Lisa Mazur to contract SSPE. Affidavits of J. Anthony Morris, Ph.D., and Kevin C. Geraghty, M.D., respectively, Mazurs' exhibit 50 and 25. Merck argues that neither man is qualified to give such an opinion. It correctly points out that neither performed any studies of his own as to the effects of a measles vaccine in humans, had any significant knowledge of SSPE or experience in treating children with SSPE before they were contacted by the Mazurs' attorneys, and had ever examined Lisa before they concluded that her illness was caused by the MMR II inoculation. Moreover, it legitimately questions Dr. Geraghty's experience in the fields of virology, neurology, and epidemiology. Merck's exhibit G at 83–84. Nonetheless, both doctors are fully qualified as experts in their chosen fields. The limited

clinical and practical experience both men have had with measles vaccines and SSPE goes to the weight to be afforded their testimony, not its admissibility. The short term, but intense study of SSPE when combined with a specialized understanding of the health hazards associated with immunization is sufficient to qualify them "by knowledge, skill, experience, training, or education" as experts in accordance with Federal Rules of Evidence 702.

Federal Rule of Evidence 703 provides that:

> The facts or data in the particular case upon which an expert bases an opinion or inference may be those perceived by or made known to the expert at or before the hearing. If of a type reasonably relied upon by experts in the particular field in forming opinions or inferences upon the subject, the facts or data need not be admissible in evidence.

In *In re Japanese Electronics Products Antitrust Litigation*, 723 F.2d 238, 275-279 (3d Cir. 1983), *rev'd on other grounds*, 475 U.S. 574, 106 S.Ct. 1348, 89 L.Ed.2d 538 (1986), the Third Circuit adopted a liberal approach to

determining what evidence is reasonably relied upon by experts in a particular field. In that case, the Third Circuit further opined that once the trial court finds that the data relied upon is of the kind upon which experts in the field reasonably rely, the trial court should not separately determine the trustworthiness of the data.

[35,36] The primary focus of a Rule 703 determination is on the soundness of the expert's methodology which leads him to a certain conclusion, rather than on the conclusion itself. *Wells v. Ortho Pharmaceutical*, 788 F.2d 741 (11th Cir.), *cert. denied*, 479 U.S. 950, 107 S.Ct. 437, 93 L.Ed.2d 386 (1986); *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1535-36 (D.C. Cir.), *cert. denied*, 469 U.S. 1062, 105 S.Ct. 545, 83 L.Ed.2d 432 (1984). Merck argues that neither expert's testimony is admissible because neither conducted his own clinical or experimental studies of MMR II and SSPE, neither examined Lisa, and both base their opinions solely

upon a short term review of the relevant medical literature. However, there is more than one way to reach an admissible expert opinion. Clinical or epidemiological studies, whether performed by the proffered expert or by other experts in the field, are not an "indispensable element in the presentation of a prima facie drug product liability case" and are not "the sole [permissible] basis for expert opinion." *Lanzilotti v. Merrell Dow Pharmaceuticals Inc.*, No. 82-0183 slip op. at 3, 1986 WL 7832 (E.D.Pa. July 10, 1986). A reasonable expert, in the absence of his own study, could turn to the medical literature in the relevant field as the basis for reaching an opinion. Moreover, in the event that a personal examination of the patient is not possible, reasonable reliance could be placed upon the reports of those doctors who did examine her. That is what both experts did in this situation. Thus, the requirements of Rule 703 have been satisfied.

The final and most persuasive challenge to the Mazurs' causation evidence is that even if both doctors are experts and both followed accepted practices in reaching their opinions, these opinions are unsupported by the studies on which they rely. Stated in legal terms, Merck contends that their opinions do not create a genuine issue of material fact.

Based upon their review of the relevant medical literature, their general understanding of the specialized fields of virology and immunology, and their review of Lisa's medical records, it is the opinion of both doctors with a reasonable degree of medical certainty that Lisa contracted SSPE as a result of the MMR II inoculation. Mazurs' exhibits 25 (Geraghty), 50 and supplemental affidavit (Morris). The opinions are unequivocal.

The medical literature on which they rely, however, does not support their conclusion. A typical statement of causation that the plaintiffs' experts rely on appears in an

article by Paul R. Dyken, M.D., where Dr. Dyken states that:

> [t]he effect of measles immunization is still not understood, but there are now some suggestions that immunization added to natural infection may create some additional worsening of the SSPE but not an earlier onset. When immunization is added to the effect of natural measles, this may induce the neurologic symptoms and possibly exacerbate them. The possibility that immunization alone produces SSPE exists, but there is no direct supportive evidence.

Dyken, *Subacute Sclerosing Panencephalitis*, Neurology Clinics, Vol. 3, No. 1, 183–84 (1985). Like the Dyken article, none of the other articles include any findings that SSPE is caused by measles vaccines, but only that there is a possible causal relationship. *See, e.g.,* Modlin, *et al., Epidemiological Studies of Measles, Measles Vaccine, and Subacute Sclerosing Panencephalitis*, Pediatrics, Vol. 59, No. 4, 509, 511 (1977) ("This study neither proves nor disproves an etiologic relationship between live, attenuated measles vaccine and SSPE.... Likewise, no virologic

evidence exists to either prove or disprove an association between measles vaccine viruses and SSPE.... Although far from conclusive, the data here presented suggests that live, attenuated measles vaccine virus may be capable of contributing to the pathogenesis of SSPE.").

> In determining whether an expert's opinion is sufficient to withstand a summary judgment motion, a court must undertake a detailed inquiry into the admissibility of the proffered testimony. *See, e.g., In re Agent Orange Product Liability Litigation*, 611 F.Supp. 1223, 1242 (E.D.N.Y. 1985), *aff'd on other grounds,* 818 F.2d 187 (2d Cir. 1987). Under Fed.R.Evid. 703, an expert is entitled to rely on the research of others and to testify therefrom. While the research and data upon which an expert relies and bases his conclusions need not themselves be admissible into evidence, a court, nonetheless, must inquire into the reliability and foundation of the expert's opinion, thereby assuring its helpfulness to the jury. *See Indian Coffee Corp. v. Procter & Gamble Co.*, 752 F.2d 891, 894–95 (3d Cir. 1985). Thus, the fact that a party has produced an expert to support its position does not preclude summary judgment. A court may enter summary judgment against a party who relies on an expert's opinion

> which is unsubstantiated and based on unsupported assumptions.

Felgenhauer v. Texaco, 1987 WL 26592, 1987 U.S. Dist. Lexis 11258 (E.D.Pa. December 1, 1987) (Ditter, J.).

[37] Here, plaintiffs' doctors are basing their opinions that to a reasonable degree of medical certainty MMR II caused Lisa's illness on medical studies that only state there is a possible link between measles vaccine and SSPE. The possibility that there is a cause and effect relationship between the two is not enough. As it is explained in *Hreha v. Benscoter*, 381 Pa.Super. 556, 554 A.2d 525, 527 (1989) (quoting *Kravinsky v. Glover*, 263 Pa.Super. 8, 396 A.2d 1349 (1979)):

> [w]hen a party must prove causation through expert testimony the expert must testify with "reasonable certainty" that "in his 'professional opinion, the result in question did come from the cause alleged.'" ... An Expert fails this standard of certainty if he testifies 'that the alleged cause "possibly", or "could have" led to the result, that it "could very properly account" for the result, or even

> that it was "very highly probable" that it caused the result.'
>
> ....
>
> "The issue is not merely one of semantics. There is a logical reason for the rule. The opinion of a[n]... expert is evidence. If the fact finder chooses to believe it, he can find as fact what the expert gave as an opinion. For a fact finder to award damages for a particular condition to a plaintiff it must find as a fact that the condition was legally caused by the defendant's conduct.... [I]t is the intent of our law that if the plaintiff's... expert cannot form an opinion with sufficient certainty so as to make a [professional] judgment, there is nothing on the record with which a [factfinder] can make a decision, with sufficient certainty, so as to make a legal judgment." (Citations omitted).

Although plaintiff's experts expressed their opinions in the appropriate legal language, them doing so was not justified by their own experiences, experiments or clinical studies. Nor did the studies of others, on which they could and did rely, support the conclusions they expressed.

This does not end the matter, however. Neither Dr. Geraghty nor Dr. Morris said he relied upon *The Merck Manual*, 2041 (Merck Sharp & Dohme Research Laboratories, 15th ed. 1987). Perhaps they should have examined it, for there the epidemiology of SSPE is stated thus: "An altered measles virus, acquired naturally or by *vaccination*, is the *probable cause*." *Id.* (emphasis added). While Drs. Geraghty and Morris were not justified in reaching their conclusions on the basis of what they did consider, what they did not consider could be helpful to them.[33]

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[33]*The Merck Manual* was not attached as one of the sources either doctor relied upon to reach his opinion. Merck also did not disclose this document to me. This text seems to undermine the credibility of Merck's arguments on causation in its motion for partial summary judgment. If Merck can include the "probable cause" statement in a published medical text, it is hard to understand the enthusiasm with which it challenges the opinions of Drs. Geraghty and Morris. Merck must have had a basis in fact for that statement. If so, Merck should have disclosed that information to the plaintiffs. I am sure it will do so now and the plaintiffs' doctors may wish to give this matter their

V. CONCLUSION

In summary, I conclude that there is no federal preemption of Pennsylvania tort claims arising out of a vaccine-related injury, that resolution of Merck's statute of limitations defense is a jury question, and, finally, I find that a decision on Merck's motion for partial summary judgment on the failure to warn claims must be reserved until further discovery is finalized and appropriate supplements are submitted to me as specified in the order which follows.

ORDER

AND NOW, this 29th day of June 1990, for the reasons set forth in the accompanying opinion, it is hereby ordered that defendant's motion for partial summary judgment and to exclude plaintiffs' expert testimony is

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renewed considerations.

denied in part. Summary judgment is denied as to the federal preemption and the statute of limitations issues. Judgment is entered in favor of plaintiffs and against defendant on the issue of federal preemption. I reserve judgment on the motion to exclude plaintiffs' expert testimony and for partial summary judgment concerning plaintiffs' duty to warn claims. The parties shall have sixty days from the date this order is filed to engage in further discovery and to supplement their respective filings, if necessary, on the duty to warn claims.